

S. 1187

At the request of Mr. DORGAN, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 1187, a bill to require the Secretary of the Treasury to mint coins in commemoration of the bicentennial of the Lewis and Clark Expedition, and for other purposes.

S. 1207

At the request of Mr. KOHL, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. 1207, a bill to amend the Internal Revenue Code of 1986 to ensure that income averaging for farmers not increase a farmer's liability for the alternative minimum tax.

S. 1244

At the request of Mr. THOMPSON, the name of the Senator from Louisiana (Ms. LANDRIEU) was added as a cosponsor of S. 1244, a bill to establish a 3-year pilot project for the General Accounting Office to report to Congress on economically significant rules of Federal agencies, and for other purposes.

SENATE CONCURRENT RESOLUTION 36

At the request of Mr. SCHUMER, the names of the Senator from Iowa (Mr. GRASSLEY), and the Senator from Pennsylvania (Mr. SANTORUM) were added as cosponsors of Senate Concurrent Resolution 36, a concurrent resolution condemning Palestinian efforts to revive the original Palestine partition plan of November 29, 1947, and condemning the United Nations Commission on Human Rights for its April 27, 1999, resolution endorsing Palestinian self-determination on the basis of the original Palestine partition plan.

SENATE CONCURRENT RESOLUTION 39

At the request of Mr. SCHUMER, the names of the Senator from Colorado (Mr. ALLARD), the Senator from New Mexico (Mr. BINGAMAN), the Senator from Kansas (Mr. BROWNBACK), the Senator from California (Mrs. FEINSTEIN), the Senator from Minnesota (Mr. GRAMS), the Senator from Nebraska (Mr. HAGEL), the Senator from Iowa (Mr. HARKIN), the Senator from Massachusetts (Mr. KENNEDY), the Senator from New Jersey (Mr. LAUTENBERG), the Senator from Connecticut (Mr. LIEBERMAN), the Senator from Maryland (Ms. MIKULSKI), the Senator from New York (Mr. MOYNIHAN), the Senator from Rhode Island (Mr. REED), the Senator from Nevada (Mr. REID), the Senator from Delaware (Mr. ROTH), the Senator from Oregon (Mr. SMITH), and the Senator from New Jersey (Mr. TORRICELLI) were added as cosponsors of Senate Concurrent Resolution 39, a concurrent resolution expressing the sense of the Congress regarding the treatment of religious minorities in the Islamic Republic of Iran, and particularly the recent arrests of members of that country's Jewish community.

SENATE RESOLUTION 99

At the request of Mr. REID, the name of the Senator from Nevada (Mr. BRYAN) was added as a cosponsor of

Senate Resolution 99, a resolution designating November 20, 1999, as "National Survivors for Prevention of Suicide Day."

SENATE RESOLUTION 115

At the request of Mr. SPECTER, his name was withdrawn as a cosponsor of Senate Resolution 115, a resolution expressing the sense of the Senate regarding United States citizens killed in terrorist attacks in Israel.

SENATE RESOLUTION 118

At the request of Mr. REID, the name of the Senator from Nevada (Mr. BRYAN) was added as a cosponsor of Senate Resolution 118, a resolution designating December 12, 1999, as "National Children's Memorial Day."

AMENDMENTS SUBMITTED

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2000

GRAHAM (AND HOLLINGS) AMENDMENT NO. 700

(Ordered to lie on the table.)

Mr. GRAHAM (for himself and Mr. HOLLINGS) submitted an amendment intended to be proposed by them to the bill (S. 1233) making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2000, and for other purposes; as follows:

On page 76, between lines 6 and 7, insert the following:

SEC. 7. INDICATION OF COUNTRY OF ORIGIN OF IMPORTED PERISHABLE AGRICULTURAL COMMODITIES.—(a) DEFINITIONS.—In this section, the terms "perishable agricultural commodity" and "retailer" have the meanings given the terms in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b)).

(b) NOTICE OF COUNTRY OF ORIGIN REQUIRED.—A retailer of a perishable agricultural commodity imported into the United States shall inform consumers, at the final point of sale of the perishable agricultural commodity to consumers, of the country of origin of the perishable agricultural commodity.

(c) METHOD OF NOTIFICATION.—

(1) IN GENERAL.—The information required by subsection (b) may be provided to consumers by means of a label, stamp, mark, placard, or other clear and visible sign on the imported perishable agricultural commodity or on the package, display, holding unit, or bin containing the commodity at the final point of sale to consumers.

(2) LABELED COMMODITIES.—If the imported perishable agricultural commodity is already individually labeled regarding country of origin by the packer, importer, or another person, the retailer shall not be required to provide any additional information to comply with this section.

(d) VIOLATIONS.—If a retailer fails to indicate the country of origin of an imported perishable agricultural commodity as required by subsection (b), the Secretary of Agriculture may impose a monetary penalty on the retailer in an amount not to exceed—

(1) \$1,000 for the first day on which the violation occurs; and

(2) \$250 for each day on which the same violation continues.

(e) DEPOSIT OF FUNDS.—Amounts collected under subsection (d) shall be deposited in the Treasury of the United States as miscellaneous receipts.

(f) APPLICATION OF SECTION.—This section shall apply with respect to a perishable agricultural commodity imported into the United States after the end of the 6-month period beginning on the date of the enactment of this section.

ABRAHAM AMENDMENT NO. 701

(Ordered to lie on the table.)

Mr. ABRAHAM submitted an amendment intended to be proposed by him to the bill, S. 1233, supra; as follows:

On page 13, line 14, before the semicolon insert the following: ", of which not less than \$600,000 shall be used to provide a special grant for bovine tuberculosis research at Michigan State University".

DASCHLE AMENDMENT NO. 702

Mr. DORGAN (for Mr. DASCHLE) proposed an amendment to the bill, S. 1233, supra; as follows:

At the appropriate place, insert the following:

TITLE —PATIENTS' BILL OF RIGHTS

SEC. 101. SHORT TITLE.

This title may be cited as the "Patients' Bill of Rights Act of 1999".

Subtitle A—Health Insurance Bill of Rights

CHAPTER 1—ACCESS TO CARE

SEC. 101. ACCESS TO EMERGENCY CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to emergency services (as defined in paragraph (2)(B)), the plan or issuer shall cover emergency services furnished under the plan or coverage—

(A) without the need for any prior authorization determination;

(B) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating health care provider without prior authorization by the plan or issuer, the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization by the plan or issuer; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) **EMERGENCY SERVICES.**—The term “emergency services” means—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in subparagraph (A)), and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(b) **REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.**—In the case of services (other than emergency services) for which benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with the guidelines established under section 1852(d)(2) of the Social Security Act (relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after an enrollee has been determined to be stable), or, in the absence of guidelines under such section, such guidelines as the Secretary shall establish to carry out this subsection), if the services are maintenance care or post-stabilization care covered under such guidelines.

SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS UNDER GROUP HEALTH PLANS.

(a) **REQUIREMENT.**—

(1) **OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.**—Except as provided in paragraph (2), if a group health plan (or health insurance coverage offered by a health insurance issuer in connection with a group health plan) provides benefits only through participating health care providers, the plan or issuer shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan or coverage and at such other times as the plan or issuer offers the participant a choice of coverage options.

(2) **EXCEPTION.**—Paragraph (1) shall not apply with respect to a participant in a group health plan if the plan offers the participant—

(A) a choice of health insurance coverage; and

(B) one or more coverage options that do not provide benefits only through participating health care providers.

(b) **POINT-OF-SERVICE COVERAGE DEFINED.**—In this section, the term “point-of-service coverage” means, with respect to benefits covered under a group health plan or health insurance issuer, coverage of such benefits when provided by a nonparticipating health care provider. Such coverage need not include coverage of providers that the plan or issuer excludes because of fraud, quality, or similar reasons.

(c) **CONSTRUCTION.**—Nothing in this section shall be construed—

(1) as requiring coverage for benefits for a particular type of health care provider;

(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options; or

(3) as preventing a group health plan or health insurance issuer from imposing high-

er premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option.

(d) **NO REQUIREMENT FOR GUARANTEED AVAILABILITY.**—If a health insurance issuer offers health insurance coverage that includes point-of-service coverage with respect to an employer solely in order to meet the requirement of subsection (a), nothing in section 2711(a)(1)(A) of the Public Health Service Act shall be construed as requiring the offering of such coverage with respect to another employer.

SEC. 103. CHOICE OF PROVIDERS.

(a) **PRIMARY CARE.**—A group health plan, and a health insurance issuer that offers health insurance coverage, shall permit each participant, beneficiary, and enrollee to receive primary care from any participating primary care provider who is available to accept such individual.

(b) **SPECIALISTS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care.

(2) **LIMITATION.**—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating providers with respect to such care.

SEC. 104. ACCESS TO SPECIALTY CARE.

(a) **OBSTETRICAL AND GYNECOLOGICAL CARE.**—

(1) **IN GENERAL.**—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider—

(A) the plan or issuer shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider; and

(B) if such an individual has not designated such a provider as a primary care provider, the plan or issuer—

(i) may not require authorization or a referral by the individual's primary care provider or otherwise for coverage of routine gynecological care (such as preventive women's health examinations) and pregnancy-related services provided by a participating health care professional who specializes in obstetrics and gynecology to the extent such care is otherwise covered, and

(ii) may treat the ordering of other gynecological care by such a participating health professional as the authorization of the primary care provider with respect to such care under the plan or coverage.

(2) **CONSTRUCTION.**—Nothing in paragraph (1)(B)(ii) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological care so ordered.

(b) **SPECIALTY CARE.**—

(1) **SPECIALTY CARE FOR COVERED SERVICES.**—

(A) **IN GENERAL.**—If—

(i) an individual is a participant or beneficiary under a group health plan or an enrollee who is covered under health insurance coverage offered by a health insurance issuer,

(ii) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist, and

(iii) benefits for such treatment are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

(B) **SPECIALIST DEFINED.**—For purposes of this subsection, the term “specialist” means, with respect to a condition, a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

(C) **CARE UNDER REFERRAL.**—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under subparagraph (A) be—

(i) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consultation with the designated primary care provider or specialist and the individual (or the individual's designee), and

(ii) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

(D) **REFERRALS TO PARTICIPATING PROVIDERS.**—A group health plan or health insurance issuer is not required under subparagraph (A) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

(E) **TREATMENT OF NONPARTICIPATING PROVIDERS.**—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to subparagraph (A), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

(2) **SPECIALISTS AS PRIMARY CARE PROVIDERS.**—

(A) **IN GENERAL.**—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care. If such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(B) **TREATMENT AS PRIMARY CARE PROVIDER.**—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in paragraph (1)(C)(i)).

(C) **ONGOING SPECIAL CONDITION DEFINED.**—In this paragraph, the term “special condition” means a condition or disease that—

(i) is life-threatening, degenerative, or disabling, and

(ii) requires specialized medical care over a prolonged period of time.

(D) **TERMS OF REFERRAL.**—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

(3) **STANDING REFERRALS.**—

(A) **IN GENERAL.**—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist.

(B) **TERMS OF REFERRAL.**—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

SEC. 105. CONTINUITY OF CARE.

(a) **IN GENERAL.**—

(1) **TERMINATION OF PROVIDER.**—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing a course of treatment from the provider at the time of such termination, the plan or issuer shall—

(A) notify the individual on a timely basis of such termination, and

(B) subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider during a transitional period (provided under subsection (b)).

(2) **TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.**—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

(3) **TERMINATION.**—In this section, the term “terminated” includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

(b) **TRANSITIONAL PERIOD.**—

(1) **IN GENERAL.**—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

(2) **INSTITUTIONAL CARE.**—The transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided

within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

(3) **PREGNANCY.**—If—

(A) a participant, beneficiary, or enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation, and

(B) the provider was treating the pregnancy before date of the termination, the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) **TERMINAL ILLNESS.**—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation, and

(B) the provider was treating the terminal illness before the date of termination, the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal illness.

(c) **PERMISSIBLE TERMS AND CONDITIONS.**—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the provider agreeing to the following terms and conditions:

(1) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(d) **CONSTRUCTION.**—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

SEC. 106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) **COVERAGE.**—

(1) **IN GENERAL.**—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

(2) **EXCLUSION OF CERTAIN COSTS.**—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(3) **USE OF IN-NETWORK PROVIDERS.**—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) **QUALIFIED INDIVIDUAL DEFINED.**—For purposes of subsection (a), the term “qualified individual” means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) **Either—**

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) **PAYMENT.**—

(1) **IN GENERAL.**—Under this section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

(2) **PAYMENT RATE.**—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate, or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) **APPROVED CLINICAL TRIAL DEFINED.**—

(1) **IN GENERAL.**—In this section, the term “approved clinical trial” means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) **CONDITIONS FOR DEPARTMENTS.**—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

SEC. 107. ACCESS TO NEEDED PRESCRIPTION DRUGS.

(a) IN GENERAL.—If a group health plan, or health insurance issuer that offers health insurance coverage, provides benefits with respect to prescription drugs but the coverage limits such benefits to drugs included in a formulary, the plan or issuer shall—

(1) ensure participation of participating physicians and pharmacists in the development of the formulary;

(2) disclose to providers and, disclose upon request under section 121(c)(6) to participants, beneficiaries, and enrollees, the nature of the formulary restrictions; and

(3) consistent with the standards for a utilization review program under section 115, provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.

(b) COVERAGE OF APPROVED DRUGS AND MEDICAL DEVICES.—

(1) IN GENERAL.—A group health plan (or health insurance coverage offered in connection with such a plan) that provides any coverage of prescription drugs or medical devices shall not deny coverage of such a drug or device on the basis that the use is investigational, if the use—

(A) in the case of a prescription drug—

(i) is included in the labeling authorized by the application in effect for the drug pursuant to subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act, without regard to any postmarketing requirements that may apply under such Act; or

(ii) is included in the labeling authorized by the application in effect for the drug under section 351 of the Public Health Service Act, without regard to any postmarketing requirements that may apply pursuant to such section; or

(B) in the case of a medical device, is included in the labeling authorized by a regulation under subsection (d) or (3) of section 513 of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act, without regard to any postmarketing requirements that may apply under such Act.

(2) CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any coverage of prescription drugs or medical devices.

SEC. 108. ADEQUACY OF PROVIDER NETWORK.

(a) IN GENERAL.—Each group health plan, and each health insurance issuer offering health insurance coverage, that provides benefits, in whole or in part, through participating health care providers shall have (in relation to the coverage) a sufficient number, distribution, and variety of qualified participating health care providers to ensure that all covered health care services, including specialty services, will be available and accessible in a timely manner to all participants, beneficiaries, and enrollees under the plan or coverage. This subsection shall only apply to a plan's or issuer's application of restrictions on the participation of health care providers in a network and shall not be construed as requiring a plan or issuer to create or establish new health care providers in an area.

(b) TREATMENT OF CERTAIN PROVIDERS.—The qualified health care providers under subsection (a) may include Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers located in the service area of the plan or issuer and shall include such providers if necessary to meet the standards established to carry out such subsection.

SEC. 109. NONDISCRIMINATION IN DELIVERY OF SERVICES.

(a) APPLICATION TO DELIVERY OF SERVICES.—Subject to subsection (b), a group health plan, and health insurance issuer in relation to health insurance coverage, may not discriminate against a participant, beneficiary, or enrollee in the delivery of health care services consistent with the benefits covered under the plan or coverage or as required by law based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as relating to the eligibility to be covered, or the offering (or guaranteeing the offer) of coverage, under a plan or health insurance coverage, the application of any pre-existing condition exclusion consistent with applicable law, or premiums charged under such plan or coverage. Pursuant to section 192(b), except as provided in section 152, nothing in this subtitle shall be construed as requiring a group health plan or health insurance issuer to provide specific benefits under the terms of such plan or coverage.

CHAPTER 2—QUALITY ASSURANCE

SEC. 111. INTERNAL QUALITY ASSURANCE PROGRAM.

(a) REQUIREMENT.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall establish and maintain an ongoing, internal quality assurance and continuous quality improvement program that meets the requirements of subsection (b).

(b) PROGRAM REQUIREMENTS.—The requirements of this subsection for a quality improvement program of a plan or issuer are as follows:

(1) ADMINISTRATION.—The plan or issuer has a separate identifiable unit with responsibility for administration of the program.

(2) WRITTEN PLAN.—The plan or issuer has a written plan for the program that is updated annually and that specifies at least the following:

(A) The activities to be conducted.

(B) The organizational structure.

(C) The duties of the medical director.

(D) Criteria and procedures for the assessment of quality.

(3) SYSTEMATIC REVIEW.—The program provides for systematic review of the type of health services provided, consistency of services provided with good medical practice, and patient outcomes.

(4) QUALITY CRITERIA.—The program—

(A) uses criteria that are based on performance and patient outcomes where feasible and appropriate;

(B) includes criteria that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate;

(C) includes methods for informing covered individuals of the benefit of preventive care and what specific benefits with respect to preventive care are covered under the plan or coverage; and

(D) makes available to the public a description of the criteria used under subparagraph (A).

(5) SYSTEM FOR REPORTING.—The program has procedures for reporting of possible quality concerns by providers and enrollees and for remedial actions to correct quality problems, including written procedures for responding to concerns and taking appropriate corrective action.

(6) DATA ANALYSIS.—The program provides, using data that include the data collected under section 112, for an analysis of the plan's or issuer's performance on quality measures.

(7) DRUG UTILIZATION REVIEW.—The program provides for a drug utilization review program in accordance with section 114.

(c) DEEMING.—For purposes of subsection (a), the requirements of—

(1) subsection (b) (other than paragraph (5)) are deemed to be met with respect to a health insurance issuer that is a qualified health maintenance organization (as defined in section 1310(c) of the Public Health Service Act); or

(2) subsection (b) are deemed to be met with respect to a health insurance issuer that is accredited by a national accreditation organization that the Secretary certifies as applying, as a condition of certification, standards at least as stringent as those required for a quality improvement program under subsection (b).

(d) VARIATION PERMITTED.—The Secretary may provide for variations in the application of the requirements of this section to group health plans and health insurance issuers based upon differences in the delivery system among such plans and issuers as the Secretary deems appropriate.

SEC. 112. COLLECTION OF STANDARDIZED DATA.

(a) IN GENERAL.—A group health plan and a health insurance issuer that offers health insurance coverage shall collect uniform quality data that include a minimum uniform data set described in subsection (b).

(b) MINIMUM UNIFORM DATA SET.—The Secretary shall specify (and may from time to time update) the data required to be included in the minimum uniform data set under subsection (a) and the standard format for such data. Such data shall include at least—

(1) aggregate utilization data;

(2) data on the demographic characteristics of participants, beneficiaries, and enrollees;

(3) data on disease-specific and age-specific mortality rates and (to the extent feasible) morbidity rates of such individuals;

(4) data on satisfaction (including satisfaction with respect to services to children) of such individuals, including data on voluntary disenrollment and grievances; and

(5) data on quality indicators and health outcomes, including, to the extent feasible and appropriate, data on pediatric cases and on a gender-specific basis.

(c) AVAILABILITY.—A summary of the data collected under subsection (a) shall be disclosed under section 121(b)(9). The Secretary shall be provided access to all the data so collected.

(d) VARIATION PERMITTED.—The Secretary may provide for variations in the application of the requirements of this section to group health plans and health insurance issuers based upon differences in the delivery system among such plans and issuers as the Secretary deems appropriate.

(e) EXCEPTION FOR NON-MEDICAL, RELIGIOUS CARE PROVIDERS.—The requirements of subsection (a), insofar as they may apply to a provider of health care, do not apply to a provider that provides no medical care and that provides only a religious method of healing or religious nonmedical nursing care.

SEC. 113. PROCESS FOR SELECTION OF PROVIDERS.

(a) **IN GENERAL.**—A group health plan and a health insurance issuer that offers health insurance coverage shall, if it provides benefits through participating health care professionals, have a written process for the selection of participating health care professionals, including minimum professional requirements.

(b) **VERIFICATION OF BACKGROUND.**—Such process shall include verification of a health care provider's license and a history of suspension or revocation.

(c) **RESTRICTION.**—Such process shall not use a high-risk patient base or location of a provider in an area with residents with poorer health status as a basis for excluding providers from participation.

(d) **NONDISCRIMINATION BASED ON LICENSURE.**—

(1) **IN GENERAL.**—Such process shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(2) **CONSTRUCTION.**—Paragraph (1) shall not be construed—

(A) as requiring the coverage under a plan or coverage of particular benefits or services or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

(B) to override any State licensure or scope-of-practice law.

(e) **GENERAL NONDISCRIMINATION.**—

(1) **IN GENERAL.**—Subject to paragraph (2), such process shall not discriminate with respect to selection of a health care professional to be a participating health care provider, or with respect to the terms and conditions of such participation, based on the professional's race, color, religion, sex, national origin, age, sexual orientation, or disability (consistent with the Americans with Disabilities Act of 1990).

(2) **RULES.**—The appropriate Secretary may establish such definitions, rules, and exceptions as may be appropriate to carry out paragraph (1), taking into account comparable definitions, rules, and exceptions in effect under employment-based nondiscrimination laws and regulations that relate to each of the particular bases for discrimination described in such paragraph.

SEC. 114. DRUG UTILIZATION PROGRAM.

A group health plan, and a health insurance issuer that provides health insurance coverage, that includes benefits for prescription drugs shall establish and maintain, as part of its internal quality assurance and continuous quality improvement program under section 111, a drug utilization program which—

(1) encourages appropriate use of prescription drugs by participants, beneficiaries, and enrollees and providers, and

(2) takes appropriate action to reduce the incidence of improper drug use and adverse drug reactions and interactions.

SEC. 115. STANDARDS FOR UTILIZATION REVIEW ACTIVITIES.

(a) **COMPLIANCE WITH REQUIREMENTS.**—

(1) **IN GENERAL.**—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.

(2) **USE OF OUTSIDE AGENTS.**—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) **UTILIZATION REVIEW DEFINED.**—For purposes of this section, the terms "utilization review" and "utilization review activities" mean procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) **WRITTEN POLICIES AND CRITERIA.**—

(1) **WRITTEN POLICIES.**—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) **USE OF WRITTEN CRITERIA.**—

(A) **IN GENERAL.**—Such a program shall utilize written clinical review criteria developed pursuant to the program with the input of appropriate physicians. Such criteria shall include written clinical review criteria described in section 111(b)(4)(B).

(B) **CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.**—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

(c) **CONDUCT OF PROGRAM ACTIVITIES.**—

(1) **ADMINISTRATION BY HEALTH CARE PROFESSIONALS.**—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions. In this subsection, the term "health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health services consistent with State law.

(2) **USE OF QUALIFIED, INDEPENDENT PERSONNEL.**—

(A) **IN GENERAL.**—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and, to the extent required, who have received appropriate training in the conduct of such activities under the program.

(B) **PEER REVIEW OF SAMPLE OF ADVERSE CLINICAL DETERMINATIONS.**—Such a program shall provide that clinical peers (as defined in section 191(c)(2)) shall evaluate the clinical appropriateness of at least a sample of adverse clinical determinations.

(C) **PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.**—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that—

(i) provides incentives, direct or indirect, for such persons to make inappropriate review decisions, or

(ii) is based, directly or indirectly, on the quantity or type of adverse determinations rendered.

(D) **PROHIBITION OF CONFLICTS.**—Such a program shall not permit a health care professional who provides health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

(3) **ACCESSIBILITY OF REVIEW.**—Such a program shall provide that appropriate per-

sonnel performing utilization review activities under the program are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) **LIMITS ON FREQUENCY.**—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

(5) **LIMITATION ON INFORMATION REQUESTS.**—Under such a program, information shall be required to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.

(d) **DEADLINE FOR DETERMINATIONS.**—

(1) **PRIOR AUTHORIZATION SERVICES.**—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(2) **CONTINUED CARE.**—In the case of a utilization review activity involving authorization for continued or extended health care services for an individual, or additional services for an individual undergoing a course of continued treatment prescribed by a health care provider, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 1 business day after the date of receipt of information that is reasonably necessary to make such determination. Such notice shall include, with respect to continued or extended health care services, the number of extended services approved, the new total of approved services, the date of onset of services, and the next review date, if any.

(3) **PREVIOUSLY PROVIDED SERVICES.**—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination.

(4) **REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, AND POST-STABILIZATION CARE.**—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see subsections (a)(1) and (b) of section 101, respectively.

(e) **NOTICE OF ADVERSE DETERMINATIONS.**—

(1) **IN GENERAL.**—Notice of an adverse determination under a utilization review program shall be provided in printed form and shall include—

(A) the reasons for the determination (including the clinical rationale);

(B) instructions on how to initiate an appeal under section 132; and

(C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such determination.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the determination in order to make a decision on such an appeal.

SEC. 116. HEALTH CARE QUALITY ADVISORY BOARD.

(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.

(b) NUMBER AND APPOINTMENT.—The advisory board shall be composed of the Secretary of Health and Human Services (or the Secretary's designee), the Secretary of Labor (or the Secretary's designee), and 20 additional members appointed by the President, in consultation with the Majority and Minority Leaders of the Senate and House of Representatives. The members so appointed shall include individuals with expertise in—

- (1) consumer needs;
- (2) education and training of health professionals;
- (3) health care services;
- (4) health plan management;
- (5) health care accreditation, quality assurance, improvement, measurement, and oversight;
- (6) medical practice, including practicing physicians;
- (7) prevention and public health; and
- (8) public and private group purchasing for small and large employers or groups.

(c) DUTIES.—The advisory board shall—

- (1) identify, update, and disseminate measures of health care quality for group health plans and health insurance issuers, including network and non-network plans;
- (2) advise the Secretary on the development and maintenance of the minimum data set in section 112(b); and
- (3) advise the Secretary on standardized formats for information on group health plans and health insurance coverage.

The measures identified under paragraph (1) may be used on a voluntary basis by such plans and issuers. In carrying out paragraph (1), the advisory board shall consult and cooperate with national health care standard setting bodies which define quality indicators, the Agency for Health Care Policy and Research, the Institute of Medicine, and other public and private entities that have expertise in health care quality.

(d) REPORT.—The advisory board shall provide an annual report to Congress and the President on the quality of the health care in the United States and national and regional trends in health care quality. Such report shall include a description of determinants of health care quality and measurements of practice and quality variability within the United States.

(e) SECRETARIAL CONSULTATION.—In serving on the advisory board, the Secretaries of Health and Human Services and Labor (or their designees) shall consult with the Secretaries responsible for other Federal health insurance and health care programs.

(f) VACANCIES.—Any vacancy on the board shall be filled in such manner as the original appointment. Members of the board shall serve without compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in the

performance of their duties. Administrative support, scientific support, and technical assistance for the advisory board shall be provided by the Secretary of Health and Human Services.

(g) CONTINUATION.—Section 14(a)(2)(B) of the Federal Advisory Committee Act (5 U.S.C. App.; relating to the termination of advisory committees) shall not apply to the advisory board.

CHAPTER 3—PATIENT INFORMATION

SEC. 121. PATIENT INFORMATION.

(a) DISCLOSURE REQUIREMENT.—

(1) GROUP HEALTH PLANS.—A group health plan shall—

(A) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) or (c) in printed form.

(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

(A) provide to individuals enrolled under such coverage at the time of enrollment, and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to enrollees, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to the applicable authority, to individuals who are prospective enrollees, and to the public the information described in subsection (b) or (c) in printed form.

(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer includes the following:

(1) SERVICE AREA.—The service area of the plan or issuer.

(2) BENEFITS.—Benefits offered under the plan or coverage, including—

(A) covered benefits, including benefit limits and coverage exclusions;

(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by non participating providers or that are furnished without meeting the applicable utilization review requirements;

(C) the extent to which benefits may be obtained from nonparticipating providers;

(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;

(E) process for determining experimental coverage; and

(F) use of a prescription drug formulary.

(3) ACCESS.—A description of the following:

(A) The number, mix, and distribution of providers under the plan or coverage.

(B) Out-of-network coverage (if any) provided by the plan or coverage.

(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 103(b)(2).

(H) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information described in this subsection and subsection (c) to such individuals and including the provision of information in a language other than English if 5 percent of the number of participants, beneficiaries, and enrollees communicate in that language instead of English.

(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.

(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(B) the process and procedures of the plan or issuer for obtaining emergency services; and

(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(6) PERCENTAGE OF PREMIUMS USED FOR BENEFITS (LOSS-RATIOS).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).

(7) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.

(8) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer, and the availability of assistance through an ombudsman to individuals in relation to group health plans and health insurance coverage.

(9) QUALITY ASSURANCE.—A summary description of the data on quality collected under section 112(a), including a summary description of the data on satisfaction of participants, beneficiaries, and enrollees (including data on individual voluntary disenrollment and grievances and appeals) described in section 112(b)(4).

(10) SUMMARY OF PROVIDER FINANCIAL INCENTIVES.—A summary description of the information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

(11) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone

numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.

(12) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under section 115, including under any drug formulary program under section 107.

(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

(3) METHOD OF PHYSICIAN COMPENSATION.—An overall summary description as to the method of compensation of participating physicians, including information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

(4) SPECIFIC INFORMATION ON CREDENTIALS OF PARTICIPATING PROVIDERS.—In the case of each participating provider, a description of the credentials of the provider.

(5) CONFIDENTIALITY POLICIES AND PROCEDURES.—A description of the policies and procedures established to carry out section 122.

(6) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

(7) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

(d) FORM OF DISCLOSURE.—

(1) UNIFORMITY.—Information required to be disclosed under this section shall be provided in accordance with uniform, national reporting standards specified by the Secretary, after consultation with applicable State authorities, so that prospective enrollees may compare the attributes of different issuers and coverage offered within an area.

(2) INFORMATION INTO HANDBOOK.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from making the information under subsections (b) and (c) available to participants, beneficiaries, and enrollees through an enrollee handbook or similar publication.

(3) UPDATING PARTICIPATING PROVIDER INFORMATION.—The information on participating health care providers described in subsection (b)(3)(C) shall be updated within such reasonable period as determined appropriate by the Secretary. Nothing in this section shall prevent an issuer from changing or updating other information made available under this section.

(e) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

SEC. 122. PROTECTION OF PATIENT CONFIDENTIALITY.

Insofar as a group health plan, or a health insurance issuer that offers health insurance coverage, maintains medical records or other health information regarding participants, beneficiaries, and enrollees, the plan or issuer shall establish procedures—

(1) to safeguard the privacy of any individually identifiable enrollee information;

(2) to maintain such records and information in a manner that is accurate and timely, and

(3) to assure timely access of such individuals to such records and information.

SEC. 123. HEALTH INSURANCE OMBUDSMEN.

(a) IN GENERAL.—Each State that obtains a grant under subsection (c) shall provide for creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers. Such Ombudsman shall be responsible for at least the following:

(1) To assist consumers in the State in choosing among health insurance coverage or among coverage options offered within group health plans.

(2) To provide counseling and assistance to enrollees dissatisfied with their treatment by health insurance issuers and group health plans in regard to such coverage or plans and with respect to grievances and appeals regarding determinations under such coverage or plans.

(b) FEDERAL ROLE.—In the case of any State that does not provide for such an Ombudsman under subsection (a), the Secretary shall provide for the creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers and that is responsible for carrying out with respect to that State the functions otherwise provided under subsection (a) by a Health Insurance Ombudsman.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services such amounts as may be necessary to provide for grants to States for contracts for Health Insurance Ombudsmen under subsection (a) or contracts for such Ombudsmen under subsection (b).

(d) CONSTRUCTION.—Nothing in this section shall be construed to prevent the use of other forms of enrollee assistance.

CHAPTER 4—GRIEVANCE AND APPEALS PROCEDURES

SEC. 131. ESTABLISHMENT OF GRIEVANCE PROCESS.

(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual's consent, regarding any aspect of the plan's or issuer's services.

(2) SCOPE.—The system shall include grievances regarding access to and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of this subtitle.

(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least 3 previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

(5) Notification to the continuous quality improvement program under section

111(a) of all grievances and appeals relating to quality of care.

SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT OF APPEAL.—

(1) IN GENERAL.—A participant or beneficiary in a group health plan, and an enrollee in health insurance coverage offered by a health insurance issuer, and any provider or other person acting on behalf of such an individual with the individual's consent, may appeal any appealable decision (as defined in paragraph (2)) under the procedures described in this section and (to the extent applicable) section 133. Such individuals and providers shall be provided with a written explanation of the appeal process and the determination upon the conclusion of the appeals process and as provided in section 121(b)(8).

(2) APPEALABLE DECISION DEFINED.—In this section, the term "appealable decision" means any of the following:

(A) Denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for a benefit, including a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(B) Failure to provide coverage of emergency services or reimbursement of maintenance care or post-stabilization care under section 101.

(C) Failure to provide a choice of provider under section 103.

(D) Failure to provide qualified health care providers under section 103.

(E) Failure to provide access to specialty and other care under section 104.

(F) Failure to provide continuation of care under section 105.

(G) Failure to provide coverage of routine patient costs in connection with an approval clinical trial under section 106.

(H) Failure to provide access to needed drugs under section 107(a)(3) or 107(b).

(I) Discrimination in delivery of services in violation of section 109.

(J) An adverse determination under a utilization review program under section 115.

(K) The imposition of a limitation that is prohibited under section 151.

(b) INTERNAL APPEAL PROCESS.—

(1) IN GENERAL.—Each group health plan and health insurance issuer shall establish and maintain an internal appeal process under which any participant, beneficiary, or enrollee, or any provider or other person acting on behalf of such an individual with the individual's consent, who is dissatisfied with any appealable decision has the opportunity to appeal the decision through an internal appeal process. The appeal may be communicated orally.

(2) CONDUCT OF REVIEW.—

(A) IN GENERAL.—The process shall include a review of the decision by a physician or other health care professional (or professionals) who has been selected by the plan or issuer and who has not been involved in the appealable decision at issue in the appeal.

(B) AVAILABILITY AND PARTICIPATION OF CLINICAL PEERS.—The individuals conducting such review shall include one or more clinical peers (as defined in section 191(c)(2)) who have not been involved in the appealable decision at issue in the appeal.

(3) DEADLINE.—

(A) IN GENERAL.—Subject to subsection (c), the plan or issuer shall conclude each appeal as soon as possible after the time of the receipt of the appeal in accordance with medical exigencies of the case involved, but in no event later than—

(i) 72 hours after the time of receipt of an expedited appeal, and

(ii) except as provided in subparagraph (B), 30 business days after such time (or, if the participant, beneficiary, or enrollee supplies additional information that was not available to the plan or issuer at the time of the receipt of the appeal, after the date of supplying such additional information) in the case of all other appeals.

(B) **EXTENSION.**—In the case of an appeal that does not relate to a decision regarding an expedited appeal and that does not involve medical exigencies, if a group health plan or health insurance issuer is unable to conclude the appeal within the time period provided under subparagraph (A)(ii) due to circumstances beyond the control of the plan or issuer, the deadline shall be extended for up to an additional 10 business days if the plan or issuer provides, on or before 10 days before the deadline otherwise applicable, written notice to the participant, beneficiary, or enrollee and the provider involved of the extension and the reasons for the extension.

(4) **NOTICE.**—If a plan or issuer denies an appeal, the plan or issuer shall provide the participant, beneficiary, or enrollee and provider involved with notice in printed form of the denial and the reasons therefore, together with a notice in printed form of rights to any further appeal.

(c) **EXPEDITED REVIEW PROCESS.**—

(1) **IN GENERAL.**—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of appeals under subsection (b) in situations in which the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee (including in the case of a child, development) or such an individual's ability to regain maximum function.

(2) **PROCESS.**—Under such procedures—

(A) the request for expedited appeal may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the appeal; and

(B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method.

(d) **DIRECT USE OF FURTHER APPEALS.**—In the event that the plan or issuer fails to comply with any of the deadlines for completion of appeals under this section or in the event that the plan or issuer for any reason expressly waives its rights to an internal review of an appeal under subsection (b), the participant, beneficiary, or enrollee involved and the provider involved shall be relieved of any obligation to complete the appeal involved and may, at such an individual's or provider's option, proceed directly to seek further appeal through any applicable external appeals process.

SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) **RIGHT TO EXTERNAL APPEAL.**—

(1) **IN GENERAL.**—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2). The appropriate Secretary shall establish standards to carry out such requirements.

(2) **EXTERNALLY APPEALABLE DECISION DEFINED.**—For purposes of this section, the term "externally appealable decision" means an appealable decision (as defined in section 132(a)(2)) if—

(A) the amount involved exceeds a significant threshold; or

(B) the patient's life or health is jeopardized (including, in the case of a child, development) as a consequence of the decision.

Such term does not include a denial of coverage for services that are specifically listed in plan or coverage documents as excluded from coverage.

(3) **EXHAUSTION OF INTERNAL APPEALS PROCESS.**—A plan or issuer may condition the use of an external appeal process in the case of an externally appealable decision upon completion of the internal review process provided under section 132, but only if the decision is made in a timely basis consistent with the deadlines provided under this chapter.

(b) **GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.**—

(1) **CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.**—

(A) **CONTRACT REQUIREMENT.**—Subject to subparagraph (B), the external appeal process under this section of a plan or issuer shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) **RESTRICTIONS ON QUALIFIED EXTERNAL APPEAL ENTITY.**—

(i) **BY STATE FOR HEALTH INSURANCE ISSUERS.**—With respect to health insurance issuers in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in such a manner as to assure an unbiased determination.

(ii) **BY FEDERAL GOVERNMENT FOR GROUP HEALTH PLANS.**—With respect to group health plans, the appropriate Secretary may exercise the same authority as a State may exercise with respect to health insurance issuers under clause (i). Such authority may include requiring the use of the qualified external appeal entity designated or selected under such clause.

(iii) **LIMITATION ON PLAN OR ISSUER SELECTION.**—If an applicable authority permits more than one entity to qualify as a qualified external appeal entity with respect to a group health plan or health insurance issuer and the plan or issuer may select among such qualified entities, the applicable authority—

(I) shall assure that the selection process will not create any incentives for external appeal entities to make a decision in a biased manner; and

(II) shall implement procedures for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(C) **OTHER TERMS AND CONDITIONS.**—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that the direct costs of the process (not including costs of representation of a participant, beneficiary, or enrollee) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee.

(2) **ELEMENTS OF PROCESS.**—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) **FAIR PROCESS; DE NOVO DETERMINATION.**—The process shall provide for a fair, de novo determination.

(B) **DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.**—A qualified external appeal entity shall determine whether a decision is an externally appealable decision and related decisions, including—

(i) whether such a decision involves an expedited appeal;

(ii) the appropriate deadlines for internal review process required due to medical exigencies in a case; and

(iii) whether such a process has been completed.

(C) **OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.**—Each party to an externally appealable decision—

(i) may submit and review evidence related to the issues in dispute.

(ii) may use the assistance or representation of one or more individuals (any of whom may be an attorney); and

(iii) may make an oral presentation.

(D) **PROVISION OF INFORMATION.**—The plan or issuer involved shall provide timely access to all its records relating to the matter of the externally appealable decision and to all provisions of the plan or health insurance coverage (including any coverage manual) relating to the matter.

(E) **TIMELY DECISIONS.**—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be binding on the plan or issuer;

(iii) be made in accordance with the medical exigencies of the case involved, but in no event later than 60 days (or 72 hours in the case of an expedited appeal) from the date of completion of the filing of notice of external appeal of the decision;

(iv) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

(v) inform the participant, beneficiary, or enrollee of the individual's rights to seek further review by the courts (or other process) of the external appeal determination.

(c) **QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.**—

(1) **IN GENERAL.**—For purposes of this section, the term "qualified external appeal entity" means, in relation to a plan or issuer, an entity (which may be a governmental entity) that is certified under paragraph (2) as meeting the following requirements:

(A) There is no real or apparent conflict of interest that would impede the entity conducting external appeal activities independent of the plan or issuer.

(B) The entity conducts external appeal activities through clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(3)(E).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) **CERTIFICATION OF EXTERNAL APPEAL ENTITIES.**—

(A) **IN GENERAL.**—In order to be treated as a qualified external appeal entity with respect to—

(i) a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1) by the Secretary of Labor (or under a process recognized or approved by the Secretary of Labor); or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements by the applicable State authority (or, if the State has not established an adequate certification and recertification process, by the Secretary of Health and Human Services,

or under a process recognized or approved by such Secretary).

(B) **RECERTIFICATION PROCESS.**—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a specification of—

(i) the information required to be submitted as a condition of recertification on the entity's performance of external appeal activities, which information shall include the number of cases reviewed, a summary of the disposition of those cases, the length of time in making determinations on those cases, and such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted; and

(ii) the periodicity which recertification will be required.

(d) **CONTINUING LEGAL RIGHTS OF ENROLLEES.**—Nothing in this subtitle shall be construed as removing any legal rights of participants, beneficiaries, enrollees, and others under State or Federal law, including the right to file judicial actions to enforce rights.

CHAPTER 5—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) **PROHIBITION.**—

(1) **GENERAL RULE.**—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or restrict the provider from engaging in medical communications with the provider's patient.

(2) **NULLIFICATION.**—Any contract provision or agreement that restricts or prohibits medical communications in violation of paragraph (1) shall be null and void.

(b) **RULES OF CONSTRUCTION.**—Nothing in this section shall be construed—

(1) to prohibit the enforcement, as part of a contract or agreement to which a health care provider is a party, of any mutually agreed upon terms and conditions, including terms and conditions requiring a health care provider to participate in, and cooperate with, all programs, policies, and procedures developed or operated by a group health plan or health insurance issuer to assure, review, or improve the quality and effective utilization of health care services (if such utilization is according to guidelines or protocols that are based on clinical or scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols under such utilization do not prohibit or restrict medical communications between providers and their patients; or

(2) to permit a health care provider to misrepresent the scope of benefits covered under the group health plan or health insurance coverage or to otherwise require a group health plan health insurance issuer to reimburse providers for benefits not covered under the plan or coverage.

(c) **MEDICAL COMMUNICATION DEFINED.**—In this section:

(1) **IN GENERAL.**—The term "medical communication" means any communication made by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) with respect to—

(A) the patient's health status, medical care, or treatment options;

(B) any utilization review requirements that may affect treatment options for the patient; or

(C) any financial incentives that may affect the treatment of the patient.

(2) **MISREPRESENTATION.**—The term "medical communication" does not include a communication by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) if the communication involves a knowing or willful misrepresentation by such provider.

SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEMNIFICATION OR IMPROPER INCENTIVE ARRANGEMENTS.

(a) **PROHIBITION OF TRANSFER OF INDEMNIFICATION.**—

(1) **IN GENERAL.**—No contract or agreement between a group health plan or health insurance issuer (or any agent acting on behalf of such a plan or issuer) and a health care provider shall contain any provision purporting to transfer to the health care provider by indemnification or otherwise any liability relating to activities, actions, or omissions of the plan, issuer, or agent (as opposed to the provider).

(2) **NULLIFICATION.**—Any contract or agreement provision described in paragraph (1) shall be null and void.

(b) **PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.**—

(1) **IN GENERAL.**—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in subparagraph (A) of such section are met with respect to such a plan.

(2) **APPLICATION.**—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION OF HEALTH CARE PROFESSIONALS.

(a) **PROCEDURES.**—Insofar as a group health plan, or health insurance issuer that offers health insurance coverage, provides benefits through participating health care professionals, the plan or issuer shall establish reasonable procedures relating to the participation (under an agreement between a professional and the plan or issuer) of such professionals under the plan or coverage. Such procedures shall include—

(1) providing notice of the rules regarding participation;

(2) providing written notice of participation decisions that are adverse to professionals; and

(3) providing a process within the plan or issuer for appealing such adverse decisions, including the presentation of information and views of the professional regarding such decision.

(b) **CONSULTATION IN MEDICAL POLICIES.**—A group health plan, and health insurance issuer that offers health insurance coverage, shall consult with participating physicians (if any) regarding the plan's or issuer's medical policy, quality, and medical management procedures.

SEC. 144. PROTECTION FOR PATIENT ADVOCACY.

(a) **PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.**—A group health plan, and a health insurance issuer with respect to the provision of health insur-

ance coverage, may not retaliate against a participant, beneficiary, enrollee, or health care provider based on the participant's, beneficiary's, enrollee's or provider's use of, or participation in, a utilization review process or a grievance process of the plan or issuer (including an internal or external review or appeal process) under this subtitle.

(b) **PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.**—

(1) **IN GENERAL.**—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional because the professional in good faith—

(A) discloses information relating to the care, services, or conditions affecting one or more participants, beneficiaries, or enrollees of the plan or issuer to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan or issuer; or

(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

(2) **GOOD FAITH ACTION.**—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

(B) the professional reasonably believes the information to be true;

(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or that a patient is in imminent hazard of loss of life or serious injury; and

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

(3) **EXCEPTION AND SPECIAL RULE.**—

(A) **GENERAL EXCEPTION.**—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

(B) **NOTICE OF INTERNAL PROCEDURES.**—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

(6) CONSTRUCTIONS.—

(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.

(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term “protected health care professional” means an individual who is a licensed or certified health care professional and who—

(A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or

(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

CHAPTER 6—PROMOTING GOOD MEDICAL PRACTICE

SEC. 151. PROMOTING GOOD MEDICAL PRACTICE.

(a) PROHIBITING ARBITRARY LIMITATIONS OR CONDITIONS FOR THE PROVISION OF SERVICES.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, may not arbitrarily interfere with or alter the decision of the treating physician regarding the manner or setting in which particular services are delivered if the services are medically necessary or appropriate for

treatment or diagnosis to the extent that such treatment or diagnosis is otherwise a covered benefit.

(2) CONSTRUCTION.—Paragraph (1) shall not be construed as prohibiting a plan or issuer from limiting the delivery of services to one or more health care providers within a network of such providers.

(3) MANNER OR SETTING DEFINED.—In paragraph (1), the term “manner or setting” means the location of treatment, such as whether treatment is provided on an inpatient or outpatient basis, and the duration of treatment, such as the number of days in a hospital. Such term does not include the coverage of a particular service or treatment.

(b) NO CHANGE IN COVERAGE.—Subsection (a) shall not be construed as requiring coverage of particular services the coverage of which is otherwise not covered under the terms of the plan or coverage or from conducting utilization review activities consistent with this subsection.

(c) MEDICAL NECESSITY OR APPROPRIATENESS DEFINED.—In subsection (a), the term “medically necessary or appropriate” means, with respect to a service or benefit, a service or benefit which is consistent with generally accepted principles of professional medical practice.

SEC. 152. STANDARDS RELATING TO BENEFITS FOR CERTAIN BREAST CANCER TREATMENT.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in his or her professional judgment consistent with generally accepted medical standards, in consultation with the patient, to be medically appropriate following—

(A) a mastectomy;

(B) a lumpectomy; or

(C) a lymph node dissection for the treatment of breast cancer.

(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not—

(1) deny to a woman eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

(2) provide monetary payments or rebates to women to encourage such women to accept less than the minimum protections available under this section;

(3) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with this section;

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section; or

(5) subject to subsection (c)(3), restrict benefits for any portion of a period within a hospital length of stay required under subsection (a) in a manner which is less favorable than the benefits provided for any preceding portion of such stay.

(c) RULES OF CONSTRUCTION.—

(1) Nothing in this section shall be construed to require a woman who is a participant or beneficiary—

(A) to undergo a mastectomy or lymph node dissection in a hospital; or

(B) to stay in the hospital for a fixed period of time following a mastectomy or lymph node dissection.

(2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissection for the treatment of breast cancer.

(3) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissection for the treatment of breast cancer under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay required under subsection (a) may not be greater than such coinsurance or cost-sharing for any preceding portion of such stay.

(d) LEVEL AND TYPE OF REIMBURSEMENTS.—Nothing in this section shall be construed to prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating the level and type of reimbursement with a provider for care provided in accordance with this section.

(e) EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1) of the Public Health Service Act) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a mastectomy performed for treatment of breast cancer and at least a 24-hour hospital length of stay following a lymph node dissection for treatment of breast cancer.

(B) Such State law requires, in connection with such coverage for surgical treatment of breast cancer, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the woman involved.

(2) CONSTRUCTION.—Section 2723(a)(1) of the Public Health Service Act and section 731(a)(1) of the Employee Retirement Income Security Act of 1974 shall not be construed as superseding a State law described in paragraph (1).

CHAPTER 7—DEFINITIONS

SEC. 191. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—The provisions of section 2971 of the Public Health Service Act shall apply for purposes of this subtitle in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term “Secretary” means the Secretary of Health and Human Services, in consultation with the Secretary of Labor and the Secretary of the Treasury and the term “appropriate Secretary” means the Secretary of Health and Human Services in relation to carrying out this subtitle under sections 2707 and 2753 of the Public Health Service Act, the Secretary of Labor in relation to carrying out this subtitle under section 714 of the Employee Retirement Income Security Act of 1974, and the Secretary of the Treasury in relation to carrying out this

subtitle under chapter 100 and section 4980D of the Internal Revenue Code of 1986.

(c) **ADDITIONAL DEFINITIONS.**—For purposes of this subtitle:

(1) **APPLICABLE AUTHORITY.**—The term “applicable authority” means—

(A) in the case of a group health plan, the Secretary of Health and Human Services and the Secretary of Labor; and

(B) in the case of a health insurance issuer with respect to a specific provision of this subtitle, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

(2) **CLINICAL PEER.**—The term “clinical peer” means, with respect to a review or appeal, a physician (allopathic or osteopathic) or other health care professional who holds a non-restricted license in a State and who is appropriately credentialed in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment rendered by a physician.

(3) **HEALTH CARE PROVIDER.**—The term “health care provider” includes a physician or other health care professional, as well as an institutional provider of health care services.

(4) **NONPARTICIPATING.**—The term “nonparticipating” means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(5) **PARTICIPATING.**—The term “participating” means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

SEC. 192. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) **CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), this subtitle shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this subtitle.

(2) **CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.**—Nothing in this subtitle shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(b) **RULES OF CONSTRUCTION.**—Except as provided in section 152, nothing in this subtitle shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(c) **DEFINITIONS.**—For purposes of this section:

(1) **STATE LAW.**—The term “State law” includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States

applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) **STATE.**—The term “State” includes a State, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

SEC. 193. REGULATIONS.

The Secretaries of Health and Human Services, Labor, and the Treasury shall issue such regulations as may be necessary or appropriate to carry out this subtitle. Such regulations shall be issued consistent with section 104 of Health Insurance Portability and Accountability Act of 1996. Such Secretaries may promulgate any interim final rules as the Secretaries determine are appropriate to carry out this subtitle.

Subtitle B—Application of Patient Protection Standards to Group Health Plans and Health Insurance Coverage Under Public Health Service Act

SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) **IN GENERAL.**—Subpart 2 of part A of title XXVII of the Public Health Service Act, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following new section:

“SEC. 2707. PATIENT PROTECTION STANDARDS.

“(a) **IN GENERAL.**—Each group health plan shall comply with patient protection requirements under subtitle A of the Patients’ Bill of Rights Act of 1999, and each health insurance issuer shall comply with patient protection requirements under such subtitle with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) **NOTICE.**—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with such notice requirement as if such section applied to such issuer and such issuer were a group health plan.”.

(b) **CONFORMING AMENDMENT.**—Section 2721(b)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg-21(b)(2)(A)) is amended by inserting “(other than section 2707)” after “requirements of such subparts”.

SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Subpart 3 of part B of title XXVII of the Public Health Service Act, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following new section:

“SEC. 2753. PATIENT PROTECTION STANDARDS.

“(a) **IN GENERAL.**—Each health insurance issuer shall comply with patient protection requirements under subtitle A of the Patients’ Bill of Rights Act of 1999 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) **NOTICE.**—A health insurance issuer under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of such subtitle as if such section applied to such issuer and such issuer were a group health plan.”.

Subtitle C—Amendments to the Employee Retirement Income Security Act of 1974

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) **IN GENERAL.**—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following:

“SEC. 714. PATIENT PROTECTION STANDARDS.

“(a) **IN GENERAL.**—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of subtitle A of the Patients’ Bill of Rights Act of 1999 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

“(b) **PLAN SATISFACTION OF CERTAIN REQUIREMENTS.**—

“(1) **SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.**—For purposes of subsection (a), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of subtitle A of the Patients’ Bill of Rights Act of 1999 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

“(A) Section 101 (relating to access to emergency care).

“(B) Section 102(a)(1) (relating to offering option to purchase point-of-service coverage), but only insofar as the plan is meeting such requirement through an agreement with the issuer to offer the option to purchase point-of-service coverage under such section.

“(C) Section 103 (relating to choice of providers).

“(D) Section 104 (relating to access to specialty care).

“(E) Section 105(a)(1) (relating to continuity in case of termination of provider contract) and section 105(a)(2) (relating to continuity in case of termination of issuer contract), but only insofar as a replacement issuer assumes the obligation for continuity of care.

“(F) Section 106 (relating to coverage for individuals participating in approved clinical trials.)

“(G) Section 107 (relating to access to needed prescription drugs).

“(H) Section 108 (relating to adequacy of provider network).

“(I) Chapter 2 of subtitle A (relating to quality assurance).

“(J) Section 143 (relating to additional rules regarding participation of health care professionals).

“(K) Section 152 (relating to standards relating to benefits for certain breast cancer treatment).

“(2) **INFORMATION.**—With respect to information required to be provided or made available under section 121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer’s failure to provide or make available the information), if

the issuer is obligated to provide and make available (or provides and makes available) such information.

“(3) GRIEVANCE AND INTERNAL APPEALS.—With respect to the grievance system and internal appeals process required to be established under sections 131 and 132, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such system and process (and is not liable for the issuer's failure to provide for such system and process), if the issuer is obligated to provide for (and provides for) such system and process.

“(4) EXTERNAL APPEALS.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 133, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.

“(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections, the group health plan shall not be liable for such violation unless the plan caused such violation:

“(A) Section 109 (relating to non-discrimination in delivery of services).

“(B) Section 141 (relating to prohibition of interference with certain medical communications).

“(C) Section 142 (relating to prohibition against transfer of indemnification or improper incentive arrangements).

“(D) Section 144 (relating to prohibition on retaliation).

“(E) Section 151 (relating to promoting good medical practice).

“(6) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

“(7) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 144(b)(1) of the Patients' Bill of Rights Act of 1999, for purposes of this subtitle the term ‘group health plan’ is deemed to include a reference to an institutional health care provider.

“(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

“(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section 144(b)(1) of the Patients' Bill of Rights Act of 1999 may file with the Secretary a complaint within 180 days of the date of the alleged retaliation or discrimination.

“(2) INVESTIGATION.—The Secretary shall investigate such complaints and shall determine if a violation of such section has occurred and, if so, shall issue an order to ensure that the protected health care professional does not suffer any loss of position, pay, or benefits in relation to the plan, issuer, or provider involved, as a result of the violation found by the Secretary.

“(d) CONFORMING REGULATIONS.—The Secretary may issue regulations to coordinate the requirements on group health plans under this section with the requirements imposed under the other provisions of this title.”.

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended by inserting

“(a)” after “SEC. 503.” and by adding at the end the following new subsection:

“(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of chapter 4 (and section 115) of subtitle A of the Patients' Bill of Rights Act of 1999 in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.”.

(c) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185(a)) is amended by striking “section 711” and inserting “sections 711 and 714”.

(2) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by inserting after the item relating to section 713 the following new item:

“Sec. 714. Patient protection standards.”.

(3) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by inserting “(other than section 144(b))” after “part 7”.

SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS INVOLVING HEALTH INSURANCE POLICY-HOLDERS.

(a) IN GENERAL.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended by adding at the end the following subsection:

“(e) PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS ARISING OUT OF PROVISION OF HEALTH BENEFITS.—

“(1) IN GENERAL.—Except as provided in this subsection, nothing in this title shall be construed to invalidate, impair, or supersede any cause of action brought by a plan participant or beneficiary (or the estate of a plan participant or beneficiary) under State law to recover damages resulting from personal injury or for wrongful death against any person—

“(A) in connection with the provision of insurance, administrative services, or medical services by such person to or for a group health plan (as defined in section 733), or

“(B) that arises out of the arrangement by such person for the provision of such insurance, administrative services, or medical services by other persons.

“(2) EXCEPTION FOR EMPLOYERS AND OTHER PLAN SPONSORS.—

“(A) IN GENERAL.—Subject to subparagraph (B), paragraph (1) does not authorize—

“(i) any cause of action against an employer or other plan sponsor maintaining the group health plan or against an employee of such an employer or sponsor acting within the scope of employment, or

“(ii) a right of recovery or indemnity by a person against an employer or other plan sponsor (or such an employee) for damages assessed against the person pursuant to a cause of action under paragraph (1).

“(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action described in paragraph (1) against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment) if—

“(i) such action is based on the employer's or other plan sponsor's (or employee's) exercise of discretionary authority to make a decision on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and

“(ii) the exercise by such employer or other plan sponsor (or employee of such authority) resulted in personal injury or wrongful death.

“(3) CONSTRUCTION.—Nothing in this subsection shall be construed as permitting a

cause of action under State law for the failure to provide an item or service which is not covered under the group health plan involved.

“(4) PERSONAL INJURY DEFINED.—For purposes of this subsection, the term ‘personal injury’ means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to acts and omissions occurring on or after the date of the enactment of this Act from which a cause of action arises.

SEC. 303. LIMITATION IN ACTIONS.

Section 502 of Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the following:

“(n)(1) Except as provided in this section, no action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of any provision in chapter 1 (other than section 109) of subtitle A, chapter 5 of subtitle A, or section 115 or 151 of the Patient's Bill of Rights Act of 1999 (as incorporated under section 714).

“(2) An action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of section 101, 104, 105, 106, 107(a)(3), 107(b), 115, or 151 of the Patient's Bill of Rights Act of 1999 (as incorporated under section 714) to the individual circumstances of that participant or beneficiary; except that—

“(A) such an action may not be brought or maintained as a class action; and

“(B) in such an action relief may only provide for the provision of (or payment for) benefits, items, or services denied to the individual participant or beneficiary involved (and for attorney's fees and the costs of the action, at the discretion of the court) and shall not provide for any other relief to the participant or beneficiary and for any relief to any other person.

“(3) Nothing in this subsection shall be construed as affecting any action brought by the Secretary.”.

Subtitle D—Application to Group Health Plans Under the Internal Revenue Code of 1986

SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 (as amended by section 1531(a) of the Taxpayer Relief Act of 1997) is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Standard relating to patient freedom of choice.”; and

(2) by inserting after section 9812 the following:

“SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

“A group health plan shall comply with the requirements of subtitle A of the Patients' Bill of Rights Act of 1999 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.”.

Subtitle E—Effective Dates; Coordination in Implementation

SEC. 501. EFFECTIVE DATES AND RELATED RULES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by sections 201(a), 301, and 401 (and subtitle A insofar as it relates to such sections) shall apply with respect to group health plans, and health insurance

coverage offered in connection with group health plans, for plan years beginning on or after October 1, 2000 (in this section referred to as the "general effective date").

(2) **TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.**—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this title, the amendments made by sections 201(a), 301, and 401 (and subtitle A insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this title shall not be treated as a termination of such collective bargaining agreement.

(b) **INDIVIDUAL HEALTH INSURANCE COVERAGE.**—The amendments made by section 202 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

(c) **TREATMENT OF RELIGIOUS NONMEDICAL PROVIDERS.**—

(1) **IN GENERAL.**—Nothing in this title (or the amendments made thereby) shall be construed to—

(A) restrict or limit the right of group health plans, and of health insurance issuers offering health insurance coverage, to include as providers religious nonmedical providers;

(B) require such plans or issuers to—

(i) utilize medically based eligibility standards or criteria in deciding provider status of religious nonmedical providers;

(ii) use medical professionals or criteria to decide patient access to religious nonmedical providers;

(iii) utilize medical professionals or criteria in making decisions in internal or external appeals regarding coverage for care by religious nonmedical providers; or

(iv) compel a participant or beneficiary to undergo a medical examination or test as a condition of receiving health insurance coverage for treatment by a religious nonmedical provider; or

(C) require such plans or issuers to exclude religious nonmedical providers because they do not provide medical or other required data, if such data is inconsistent with the religious nonmedical treatment or nursing care provided by the provider.

(2) **RELIGIOUS NONMEDICAL PROVIDER.**—For purposes of this subsection, the term "religious nonmedical provider" means a provider who provides no medical care but who provides only religious nonmedical treatment or religious nonmedical nursing care.

SEC. 502. COORDINATION IN IMPLEMENTATION.

Section 104(1) of Health Insurance Portability and Accountability Act of 1996 is amended by striking "this subtitle (and the amendments made by this subtitle and section 401)" and inserting "the provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, the provisions of parts A and C of title XXVII of the Public Health Service Act, chapter 100 of the Internal Revenue Code of 1986, and subtitle A of the Patients' Bill of Rights Act of 1999".

SEC. 503. NO IMPACT ON SOCIAL SECURITY TRUST FUND.

(a) **IN GENERAL.**—Nothing in this title shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

(b) **TRANSFERS.**—

(1) **ESTIMATE OF SECRETARY.**—The Secretary of the Treasury shall annually estimate the impact that the enactment of this title has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

(2) **TRANSFER OF FUNDS.**—If, under paragraph (1), the Secretary of the Treasury estimates that the enactment of this title has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such title.

Subtitle F—Revenue-Related Provisions

SEC. 601. INFORMATION REQUIREMENTS.

(a) **INFORMATION FROM GROUP HEALTH PLANS.**—Section 1862(b) of the Social Security Act (42 U.S.C. 1395y(b)) is amended by adding at the end the following:

"(7) **INFORMATION FROM GROUP HEALTH PLANS.**—

"(A) **PROVISION OF INFORMATION BY GROUP HEALTH PLANS.**—The administrator of a group health plan subject to the requirements of paragraph (1) shall provide to the Secretary such of the information elements described in subparagraph (C) as the Secretary specifies, and in such manner and at such times as the Secretary may specify (but not more frequently than 4 times per year), with respect to each individual covered under the plan who is entitled to any benefits under this title.

"(B) **PROVISION OF INFORMATION BY EMPLOYERS AND EMPLOYEE ORGANIZATIONS.**—An employer (or employee organization) that maintains or participates in a group health plan subject to the requirements of paragraph (1) shall provide to the administrator of the plan such of the information elements required to be provided under subparagraph (A), and in such manner and at such times as the Secretary may specify, at a frequency consistent with that required under subparagraph (A) with respect to each individual described in subparagraph (A) who is covered under the plan by reason of employment with that employer or membership in the organization.

"(C) **INFORMATION ELEMENTS.**—The information elements described in this subparagraph are the following:

"(i) **ELEMENTS CONCERNING THE INDIVIDUAL.**—

"(I) The individual's name.

"(II) The individual's date of birth.

"(III) The individual's sex.

"(IV) The individual's social security insurance number.

"(V) The number assigned by the Secretary to the individual for claims under this title.

"(VI) The family relationship of the individual to the person who has or had current or employment status with the employer.

"(ii) **ELEMENTS CONCERNING THE FAMILY MEMBER WITH CURRENT OR FORMER EMPLOYMENT STATUS.**—

"(I) The name of the person in the individual's family who has current or former employment status with the employer.

"(II) That person's social security insurance number.

"(III) The number or other identifier assigned by the plan to that person.

"(IV) The periods of coverage for that person under the plan.

"(V) The employment status of that person (current or former) during those periods of coverage.

"(VI) The classes (of that person's family members) covered under the plan.

"(iii) **PLAN ELEMENTS.**—

"(I) The items and services covered under the plan.

"(II) The name and address to which claims under the plan are to be sent.

"(iv) **ELEMENTS CONCERNING THE EMPLOYER.**—

"(I) The employer's name.

"(II) The employer's address.

"(III) The employer identification number of the employer.

"(D) **USE OF IDENTIFIERS.**—The administrator of a group health plan shall utilize a unique identifier for the plan in providing information under subparagraph (A) and in other transactions, as may be specified by the Secretary, related to the provisions of this subsection. The Secretary may provide to the administrator the unique identifier described in the preceding sentence.

"(E) **PENALTY FOR NONCOMPLIANCE.**—Any entity that knowingly and willfully fails to comply with a requirement imposed by the previous subparagraphs shall be subject to a civil money penalty not to exceed \$1,000 for each incident of such failure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as those provisions apply to a penalty or proceeding under section 1128A(a)."

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

SEC. 602. EXTENSION OF HAZARDOUS SUBSTANCE SUPERFUND TAXES.

(a) **EXTENSION OF TAXES.**—

(1) **ENVIRONMENTAL TAX.**—Section 59A(e) of the Internal Revenue Code of 1986 is amended to read as follows:

"(e) **APPLICATION OF TAX.**—The tax imposed by this section shall apply to taxable years beginning after December 31, 1986, and before January 1, 1996, and to taxable years beginning after December 31, 1998, and before January 1, 2010."

(2) **EXCISE TAXES.**—Section 4611(e) of such Code is amended to read as follows:

"(e) **APPLICATION OF HAZARDOUS SUBSTANCE SUPERFUND FINANCING RATE.**—The Hazardous Substance Superfund financing rate under this section shall apply after December 31, 1986, and before January 1, 1996, and after September 15, 1999, and before October 1, 2009."

(b) **EFFECTIVE DATES.**—

(1) **INCOME TAX.**—The amendment made by subsection (a)(1) shall apply to taxable years beginning after December 31, 1998.

(2) **EXCISE TAX.**—The amendment made by subsection (a)(2) shall take effect on September 15, 1999.

SEC. 603. MODIFICATION TO FOREIGN TAX CREDIT CARRYBACK AND CARRY-FORWARD PERIODS.

(a) **IN GENERAL.**—Section 904(c) of the Internal Revenue Code of 1986 (relating to limitation on credit) is amended—

(1) by striking "in the second preceding taxable year," and

(2) by striking "or fifth" and inserting "fifth, sixth, or seventh".

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply to credits arising in taxable years beginning after December 31, 2001.

SEC. 604. LIMITATIONS ON WELFARE BENEFIT FUNDS OF 10 OR MORE EMPLOYER PLANS.

(a) **BENEFITS TO WHICH EXCEPTION APPLIES.**—Section 419A(f)(6)(A) of the Internal

Revenue Code of 1986 (relating to exception for 10 or more employer plans) is amended to read as follows:

“(A) IN GENERAL.—This subpart shall not apply to a welfare benefit fund which is part of a 10 or more employer plan if the only benefits provided through the fund are 1 or more of the following:

“(i) Medical benefits.

“(ii) Disability benefits.

“(iii) Group term life insurance benefits which do not provide for any cash surrender value or other money that can be paid, assigned, borrowed, or pledged for collateral for a loan.

The preceding sentence shall not apply to any plan which maintains experience-rating arrangements with respect to individual employers.”

(b) LIMITATION ON USE OF AMOUNTS FOR OTHER PURPOSES.—Section 4976(b) of the Internal Revenue Code of 1986 (defining disqualified benefit) is amended by adding at the end the following new paragraph:

“(5) SPECIAL RULE FOR 10 OR MORE EMPLOYER PLANS EXEMPTED FROM PREFUNDING LIMITS.—For purposes of paragraph (1)(C), if—

“(A) subpart D of part I of subchapter D of chapter 1 does not apply by reason of section 419A(f)(6) to contributions to provide 1 or more welfare benefits through a welfare benefit fund under a 10 or more employer plan, and

“(B) any portion of the welfare benefit fund attributable to such contributions is used for a purpose other than that for which the contributions were made,

then such portion shall be treated as reverting to the benefit of the employers maintaining the fund.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to contributions paid or accrued after the date of the enactment of this Act, in taxable years ending after such date.

SEC. 605. MODIFICATION OF INSTALLMENT METHOD AND REPEAL OF INSTALLMENT METHOD FOR ACCRUAL METHOD TAXPAYERS.

(a) REPEAL OF INSTALLMENT METHOD FOR ACCRUAL BASIS TAXPAYERS.—

(1) IN GENERAL.—Subsection (a) of section 453 of the Internal Revenue Code of 1986 (relating to installment method) is amended to read as follows:

“(a) USE OF INSTALLMENT METHOD.—

“(1) IN GENERAL.—Except as otherwise provided in this section, income from an installment sale shall be taken into account for purposes of this title under the installment method.

“(2) ACCRUAL METHOD TAXPAYER.—The installment method shall not apply to income from an installment sale if such income would be reported under an accrual method of accounting without regard to this section. The preceding sentence shall not apply to a disposition described in subparagraph (A) or (B) of subsection (1)(2).”

(2) CONFORMING AMENDMENTS.—Sections 453(d)(1), 453(i)(1), and 453(k) of the Internal Revenue Code of 1986 are each amended by striking “(a)” each place it appears and inserting “(a)(1)”.

(b) MODIFICATION OF PLEDGE RULES.—Paragraph (4) of section 453A(d) (relating to pledges, etc., of installment obligations) is amended by adding at the end the following: “A payment shall be treated as directly secured by an interest in an installment obligation to the extent an arrangement allows the taxpayer to satisfy all or a portion of the indebtedness with the installment obligation.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to sales or

other dispositions occurring on or after the date of the enactment of this Act.

LOTT AMENDMENT NO. 703

Mr. LOTT proposed an amendment to amendment No. 702 proposed by Mr. DASCHLE to the bill, S. 1233, *supra*; as follows:

Beginning on page 1 of the amendment, line 2, strike all after the first word and insert the following:

—ACCESS TO QUALITY, AFFORDABLE HEALTH CARE

SEC. 101. SHORT TITLE.

This title may be cited as the “Patients’ Bill of Rights Plus Act”.

Subtitle A—Patients’ Bill of Rights

CHAPTER 1—RIGHT TO ADVICE AND CARE

SEC. 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.

(a) IN GENERAL.—Part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et seq.) is amended—

(1) by redesignating subpart C as subpart D; and

(2) by inserting after subpart B the following:

“Subpart C—Patient Right to Medical Advice and Care

“SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL CARE.

“(a) IN GENERAL.—To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (as defined in subsection (c)), except for items or services specifically excluded—

“(1) the plan shall provide coverage for benefits, without requiring preauthorization, for appropriate emergency medical screening examinations (within the capability of the emergency facility, including ancillary services routinely available to the emergency facility) to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary to determine whether emergency medical care (as so defined) is necessary; and

“(2) the plan shall provide coverage for benefits, without requiring preauthorization, for additional emergency medical care to stabilize an emergency medical condition following an emergency medical screening examination (if determined necessary under paragraph (1)), pursuant to the definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

“(b) UNIFORM COST-SHARING REQUIRED AND OUT-OF-NETWORK CARE.—

“(1) UNIFORM COST-SHARING.—Nothing in this section shall be construed as preventing a group health plan (other than a fully insured group health plan) from imposing any form of cost-sharing applicable to any participant or beneficiary (including coinsurance, copayments, deductibles, and any other charges) in relation to coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, with respect to similarly situated participants and beneficiaries, to all benefits consisting of emergency medical care (as defined in subsection (c)) provided to such similarly situated participants and beneficiaries under the plan.

“(2) OUT-OF-NETWORK CARE.—If a group health plan (other than a fully insured group health plan) provides any benefits with respect to emergency medical care (as defined in subsection (c)), the plan shall cover emergency medical care under the plan in a manner so that, if such care is provided to a par-

ticipant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating provider.

“(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In this section:

“(1) IN GENERAL.—The term ‘emergency medical care’ means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient services that—

“(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such services; and

“(B) are needed to evaluate or stabilize (as such term is defined in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)) an emergency medical condition (as defined in paragraph (2)).

“(2) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

“(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

“(B) serious impairment to bodily functions, or

“(C) serious dysfunction of any bodily organ or part.

“SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.

“(a) REQUIREMENT.—

“(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

“(2) EXCEPTION IN THE CASE OF MULTIPLE ISSUER OR COVERAGE OPTIONS.—Paragraph (1) shall not apply with respect to a participant in a group health plan (other than a fully insured group health plan) if the plan offers the participant 2 or more coverage options that differ significantly with respect to the use of participating health care professionals or the networks of such professionals that are used.

“(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term ‘point-of-service coverage’ means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

“(c) SMALL EMPLOYER EXEMPTION.—

“(1) IN GENERAL.—This section shall not apply to any group health plan (other than a fully insured group health plan) of a small employer.

“(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term ‘small employer’ means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a

plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

“(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed—

“(1) as requiring coverage for benefits for a particular type of health care professional;

“(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

“(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

“(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

“SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

“(a) **GENERAL RIGHTS.**—

“(1) **WAIVER OF PLAN REFERRAL REQUIREMENT.**—If a group health plan described in subsection (b) requires a referral to obtain coverage for specialty care, the plan shall waive the referral requirement in the case of a female participant or beneficiary who seeks coverage for routine obstetrical care or routine gynecological care.

“(2) **RELATED ROUTINE CARE.**—With respect to a participant or beneficiary described in paragraph (1), a group health plan described in subsection (b) shall treat the ordering of other routine care that is related to routine obstetric or gynecologic care, by a physician who specializes in obstetrics and gynecology as the authorization of the primary care provider for such other routine care.

“(b) **APPLICATION OF SECTION.**—A group health plan described in this subsection is a group health plan (other than a fully insured group health plan), that—

“(1) provides coverage for routine obstetric care (such as pregnancy-related services) or routine gynecologic care (such as preventive women's health examinations); and

“(2) requires the designation by a participant or beneficiary of a participating primary care provider who is not a physician who specializes in obstetrics or gynecology.

“(c) **RULES OF CONSTRUCTION.**—Nothing in this section shall be construed—

“(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of obstetric or gynecologic care described in subsection (a);

“(2) to preclude the plan from requiring that the physician who specializes in obstetrics or gynecology notify the designated primary care provider or the plan of treatment decisions; or

“(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine obstetric or routine gynecologic care.

“SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.

“(a) **IN GENERAL.**—In the case of a group health plan (other than a fully insured group health plan) that provides coverage for routine pediatric care and that requires the designation by a participant or beneficiary of a participating primary care provider, if the designated primary care provider is not a physician who specializes in pediatrics—

“(1) the plan may not require authorization or referral by the primary care provider

in order for a participant or beneficiary to obtain coverage for routine pediatric care; and

“(2) the plan shall treat the ordering of other routine care related to routine pediatric care by such a specialist as having been authorized by the designated primary care provider.

“(b) **RULES OF CONSTRUCTION.**—Nothing in subsection (a) shall be construed—

“(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of any pediatric care provided to, or ordered for, a participant or beneficiary;

“(2) to preclude a group health plan from requiring that a specialist described in subsection (a) notify the designated primary care provider or the plan of treatment decisions; or

“(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine pediatric care.

“SEC. 725. ACCESS TO SPECIALISTS.

“(a) **IN GENERAL.**—A group health plan (other than a fully insured group health plan) shall ensure that participants and beneficiaries have access to specialty care when such care is covered under the plan. Such access may be provided through contractual arrangements with specialized providers outside of the network of the plan.

“(b) **TREATMENT PLANS.**—

“(1) **IN GENERAL.**—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring that specialty care be provided pursuant to a treatment plan so long as the treatment plan is—

“(A) developed by the specialist, in consultation with the primary care provider, and the participant or beneficiary;

“(B) approved by the plan; and

“(C) in accordance with the applicable quality assurance and utilization review standards of the plan.

“(2) **NOTIFICATION.**—Nothing in paragraph (1) shall be construed as prohibiting a plan from requiring the specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all other necessary medical information.

“(c) **REFERRALS.**—Nothing in this section shall be construed to prohibit a plan from requiring an authorization by the primary care provider of the participant or beneficiary in order to obtain coverage for specialty services so long as such authorization is for an adequate number of referrals under an approved treatment plan if such a treatment plan is required by the plan.

“(d) **SPECIALTY CARE DEFINED.**—For purposes of this subsection, the term “specialty care” means, with respect to a condition, care and treatment provided by a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

“SEC. 726. CONTINUITY OF CARE.

“(a) **IN GENERAL.**—

“(1) **TERMINATION OF PROVIDER.**—If a contract between a group health plan (other than a fully insured group health plan) and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

“(A) notify the individual on a timely basis of such termination;

“(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

“(C) in the case of termination described in paragraph (2), (3), or (4) of subsection (b), and subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

“(2) **TERMINATED.**—In this section, the term “terminated” includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

“(3) **CONTRACTS.**—For purposes of this section, the term “contract between a group health plan (other than a fully insured group health plan) and a health care provider” shall include a contract between such a plan and an organized network of providers.

“(b) **TRANSITIONAL PERIOD.**—

“(1) **GENERAL RULE.**—Except as provided in paragraph (3), the transitional period under this subsection shall permit the participant or beneficiary to extend the coverage involved for up to 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

“(2) **INSTITUTIONAL CARE.**—Subject to paragraph (1), the transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

“(3) **PREGNANCY.**—Notwithstanding paragraph (1), if—

“(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

“(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(4) **TERMINAL ILLNESS.**—Subject to paragraph (1), if—

“(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) prior to a provider's termination of participation; and

“(B) the provider was treating the terminal illness before the date of termination; the transitional period under this subsection shall be for care directly related to the treatment of the terminal illness.

“(c) **PERMISSIBLE TERMS AND CONDITIONS.**—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by a provider under subsection (a)(1)(C) upon the provider agreeing to the following terms and conditions:

“(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed

the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

“(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

“(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

“(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

“(e) **DEFINITION.**—In this section, the term ‘health care provider’ or ‘provider’ means—

“(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

“(2) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

“SEC. 727. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

“(a) **IN GENERAL.**—Subject to subsection (b), a group health plan (other than a fully insured group health plan and in relation to a participant or beneficiary) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the participant or beneficiary or medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

“(b) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

“SEC. 728. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.

“To the extent that a group health plan (other than a fully insured group health plan) provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan shall—

“(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

“(2) in accordance with the applicable quality assurance and utilization review standards of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

“SEC. 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES.

“(a) **IN GENERAL.**—A group health plan (other than a fully insured group health plan) may not—

“(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral health care services once the plan has denied coverage for such services; or

“(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services—

“(A) that are not otherwise covered under the plan; or

“(B) for which the group health plan provides limited coverage, to the extent that the group health plan denies coverage of the services.

“(b) **RULE OF CONSTRUCTION.**—Nothing in subsection (a)(2)(B) shall be construed as prohibiting a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

“SEC. 730. GENERALLY APPLICABLE PROVISION.

“In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of this subpart, other than section 722, shall apply separately with respect to each coverage option.”.

(b) RULE WITH RESPECT TO CERTAIN PLANS.—

(1) **IN GENERAL.**—Notwithstanding any other provision of law, health insurance issuers may offer, and eligible individuals may purchase, high deductible health plans described in section 220(c)(2)(A) of the Internal Revenue Code of 1986. Effective for the 4-year period beginning on the date of the enactment of this Act, such health plans shall not be required to provide payment for any health care items or services that are exempt from the plan's deductible.

(2) **EXISTING STATE LAWS.**—A State law relating to payment for health care items and services in effect on the date of enactment of this Act that is preempted under paragraph (1), shall not apply to high deductible health plans after the expiration of the 4-year period described in such paragraph unless the State reenacts such law after such period.

(c) **DEFINITION.**—Section 733(a) of the Employee Retirement Income Security Act of 1974 (42 U.S.C. 1191(a)) is amended by adding at the end the following:

“(3) **FULLY INSURED GROUP HEALTH PLAN.**—The term ‘fully insured group health plan’ means a group health plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.”.

(d) **CONFORMING AMENDMENT.**—The table of contents in section 1 of such Act is amended—

(1) in the item relating to subpart C, by striking “Subpart C” and inserting “Subpart D”; and

(2) by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such Act the following new items:

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Access to specialists.

“Sec. 726. Continuity of care.

“Sec. 727. Protection of patient-provider communications.

“Sec. 728. Patient's right to prescription drugs.

“Sec. 729. Self-payment for behavioral health care services.

“Sec. 730. Generally applicable provisions.”.

SEC. 102. COMPREHENSIVE INDEPENDENT STUDY OF PATIENT ACCESS TO CLINICAL TRIALS AND COVERAGE OF ASSOCIATED ROUTINE COSTS.

(a) **STUDY BY THE INSTITUTE OF MEDICINE.**—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall enter into a contract with the Institute of Medicine to con-

duct a comprehensive study of patient access to clinical trials and the coverage of routine patient care costs by private health plans and insurers.

(b) **MATTERS TO BE ASSESSED.**—The study shall assess the following:

(1) The factors that hinder patient participation in clinical trials, including health plan and insurance policies and practices.

(2) The ability of health plans and investigators to distinguish between routine patient care costs and costs associated with clinical trials.

(3) The potential impact of health plan coverage of routine costs associated with clinical trials on health care premiums.

(c) REPORT.—

(1) **IN GENERAL.**—Not later than 12 months after the date of the execution of the contract referred to in subsection (a), the Institute of Medicine shall submit a report on the study conducted pursuant to that contract to the Committee on Health, Education, Labor and Pensions of the Senate.

(2) **MATTERS INCLUDED.**—The report submitted under paragraph (1) shall set forth the findings, conclusions, and recommendations of the Institute of Medicine for—

(A) increasing patient participation in clinical trials;

(B) encouraging collaboration between the public and private sectors; and

(C) improving analysis of determining routine costs associated with the conduct of clinical trials.

(3) **COPY TO SECRETARY.**—Concurrent with the submission of the report under paragraph (1), the Institute of Medicine shall transmit a copy of the report to the Secretary.

(d) **FUNDING.**—Out of funds appropriated to the Department of Health and Human Services for fiscal year 2000, the Secretary shall provide for such funding as the Secretary determines is necessary in order to carry out the study and report by the Institute of Medicine under this section.

SEC. 103. EFFECTIVE DATE AND RELATED RULES.

(a) **IN GENERAL.**—The amendments made by this chapter shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

(b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No enforcement action shall be taken, pursuant to the amendments made by this chapter, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of title B of part 7 of subtitle B of title I of such Act the following new items:

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Access to specialists.

“Sec. 726. Continuity of care.

“Sec. 727. Protection of patient-provider communications.

“Sec. 728. Patient's right to prescription drugs.

“Sec. 729. Self-payment for behavioral health care services.

“Sec. 730. Generally applicable provisions.”.

SEC. 102. COMPREHENSIVE INDEPENDENT STUDY OF PATIENT ACCESS TO CLINICAL TRIALS AND COVERAGE OF ASSOCIATED ROUTINE COSTS.

(a) **STUDY BY THE INSTITUTE OF MEDICINE.**—Not later than 30 days after the date of enactment of this Act, the Secretary of Health

and Human Services (in this section referred to as the "Secretary") shall enter into a contract with the Institute of Medicine to conduct a comprehensive study of patient access to clinical trials and the coverage of routine patient care costs by private health plans and insurers.

(b) **MATTERS TO BE ASSESSED.**—The study shall assess the following:

(1) The factors that hinder patient participation in clinical trials, including health plan and insurance policies and practices.

(2) The ability of health plans and investigators to distinguish between routine patient care costs and costs associated with clinical trials.

(3) The potential impact of health plan coverage of routine costs associated with clinical trials on health care premiums.

(c) **REPORT.**—

(1) **IN GENERAL.**—Not later than 12 months after the date of the execution of the contract referred to in subsection (a), the Institute of Medicine shall submit a report on the study conducted pursuant to that contract to the Committee on Health, Education, Labor and Pensions of the Senate.

(2) **MATTERS INCLUDED.**—The report submitted under paragraph (1) shall set forth the findings, conclusions, and recommendations of the Institute of Medicine for—

(A) increasing patient participation in clinical trials;

(B) encouraging collaboration between the public and private sectors; and

(C) improving analysis of determining routine costs associated with the conduct of clinical trials.

(3) **COPY TO SECRETARY.**—Concurrent with the submission of the report under paragraph (1), the Institute of Medicine shall transmit a copy of the report to the Secretary.

(d) **FUNDING.**—Out of funds appropriated to the Department of Health and Human Services for fiscal year 2000, the Secretary shall provide for such funding as the Secretary determines is necessary in order to carry out the study and report by the Institute of Medicine under this section.

SEC. 103. EFFECTIVE DATE AND RELATED RULES.

(a) **IN GENERAL.**—The amendments made by this chapter shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

(b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No enforcement action shall be taken, pursuant to the amendments made by this chapter, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of "(III) The number or other identifier assigned by the plan to that person."

"(IV) The periods of coverage for that person under the plan."

"(V) The employment status of that person (current or former) during those periods of coverage."

"(VI) The classes (of that person's family members) covered under the plan."

"(iii) **PLAN ELEMENTS.**—

"(I) The items and services covered under the plan."

"(II) The name and address to which claims under the plan are to be sent."

"(iv) **ELEMENTS CONCERNING THE EMPLOYER.**—

"(I) The employer's name."

"(II) The employer's address."

"(III) The employer identification number of the employer."

"(D) **USE OF IDENTIFIERS.**—The administrator of a group health plan shall utilize a unique identifier for the plan in providing in-

formation under subparagraph (A) and in other transactions, as may be specified by the Secretary, related to the provisions of this subsection. The Secretary may provide to the administrator the unique identifier described in the preceding sentence.

"(E) **PENALTY FOR NONCOMPLIANCE.**—Any entity that knowingly and willfully fails to comply with a requirement imposed by the previous subparagraphs shall be subject to a civil money penalty not to exceed \$1,000 for each incident of such failure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as those provisions apply to a penalty or proceeding under section 1128A(a)."

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

SEC. 602. EXTENSION OF HAZARDOUS SUBSTANCE SUPERFUND TAXES.

(a) **EXTENSION OF TAXES.**—

(1) **ENVIRONMENTAL TAX.**—Section 59A(e) of the Internal Revenue Code of 1986 is amended to read as follows:

"(e) **APPLICATION OF TAX.**—The tax imposed by this section shall apply to taxable years beginning after December 31, 1986, and before January 1, 1996, and to taxable years beginning after December 31, 1998, and before January 1, 2010."

(2) **EXCISE TAXES.**—Section 4611(e) of such Code is amended to read as follows:

"(e) **APPLICATION OF HAZARDOUS SUBSTANCE SUPERFUND FINANCING RATE.**—The Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers and that is responsible for carrying out with respect to that State the functions otherwise provided under subsection (a) by a Health Insurance Ombudsman."

(c) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to the Secretary of Health and Human Services such amounts as may be necessary to provide for grants to States for contracts for Health Insurance Ombudsmen under subsection (a) or contracts for such Ombudsmen under subsection (b).

(d) **CONSTRUCTION.**—Nothing in this section shall be construed to prevent the use of other forms of enrollee assistance.

CHAPTER 4—GRIEVANCE AND APPEALS PROCEDURES

SEC. 131. ESTABLISHMENT OF GRIEVANCE PROCESS.

(a) **ESTABLISHMENT OF GRIEVANCE SYSTEM.**—

(1) **IN GENERAL.**—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual's consent, regarding any aspect of the plan's or issuer's services.

(2) **SCOPE.**—The system shall include grievances regarding access to and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of this subtitle.

(b) **GRIEVANCE SYSTEM.**—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer

personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least 3 previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

(5) Notification to the continuous quality improvement program under section 111(a) of all grievances and appeals relating to quality of care.

SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) **RIGHT OF APPEAL.**—

(1) **IN GENERAL.**—A participant or beneficiary in a group health plan, and an enrollee in health insurance coverage offered by a health insurance issuer, and any provider or other person acting on behalf of such an individual regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

CHAPTER 2—RIGHT TO INFORMATION ABOUT PLANS AND PROVIDERS

SEC. 111. INFORMATION ABOUT PLANS.

(a) **EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.**—

(1) **IN GENERAL.**—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following:

"SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.

"(a) **REQUIREMENT.**—

"(1) **IN GENERAL.**—A group health plan, and a health insurance issuer that provides coverage in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, of the information described in subsection (b)."

"(2) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to prevent a plan or issuer from entering into any agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance."

"(3) **PROVISION OF INFORMATION.**—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan or issuer with respect to such participants or beneficiaries."

"(b) **REQUIRED INFORMATION.**—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

"(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan."

"(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan."

"(3) A description of any optional supplemental benefits offered by each such plan"

and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

“(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

“(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

“(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

“(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

“(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

“(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

“(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

“(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

“(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

“(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

“(14) A description of the specific preventative services covered under the plan if such services are covered.

“(15) A statement regarding—

“(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

“(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

“(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

“(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

“(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

“(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring

plans to provide information concerning proprietary payment methodology.

“(D) A summary description of the procedures used for utilization review.

“(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

“(F) A description of the specific exclusions from coverage under the plan.

“(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

“(H) Any information that is made public by accrediting organizations in the process of accreditation if the plan is accredited, or any additional quality indicators that the plan makes available.

“(C) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

“(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan, or health insurance issuer in connection with group health insurance coverage, from distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

“(e) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

“(f) HEALTH CARE PROFESSIONAL.—In this section, the term ‘health care professional’ means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.”.

(2) CONFORMING AMENDMENTS.—

(A) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking “section 711, and inserting “sections 711 and 714”.

(B) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001) is amended by inserting after the item relating to section 713, the following:

“Sec. 714. Health plan comparative information.”.

(b) INTERNAL REVENUE CODE OF 1986.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Health plan comparative information.”; and

(2) by inserting after section 9812 the following:

“SEC. 9813. HEALTH PLAN COMPARATIVE INFORMATION.

“(a) REQUIREMENT.—

“(1) IN GENERAL.—A group health plan shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, of the information described in subsection (b).

“(2) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan from entering into any agreement under which a health insurance issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

“(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan with respect to such participants or beneficiaries.

“(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

“(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

“(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

“(3) A description of any optional supplemental benefits offered by each such plan and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

“(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

“(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

“(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

“(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

“(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

“(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

“(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

“(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

“(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

“(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

“(14) A description of the specific preventative services covered under the plan if such services are covered.

“(15) A statement regarding—

“(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

“(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

“(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

“(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

“(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

“(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

“(D) A summary description of the procedures used for utilization review.

“(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

“(F) A description of the specific exclusions from coverage under the plan.

“(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

“(H) Any information that is made public by accrediting organizations in the process of accreditation if the plan is accredited, or any additional quality indicators that the plan makes available.

“(C) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

“(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan from distributing any other additional information determined by the plan to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

“(e) HEALTH CARE PROFESSIONAL.—In this section, the term ‘health care professional’ means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or

occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.”.

SEC. 112. INFORMATION ABOUT PROVIDERS.

(a) STUDY.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for the conduct of a study, and the submission to the Secretary of a report, that includes—

(1) an analysis of information concerning health care professionals that is currently available to patients, consumers, States, and professional societies, nationally and on a State-by-State basis, including patient preferences with respect to information about such professionals and their competencies;

(2) an evaluation of the legal and other barriers to the sharing of information concerning health care professionals; and

(3) recommendations for the disclosure of information on health care professionals, including the competencies and professional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall forward to the appropriate committees of Congress a copy of the report and study conducted under subsection (a).

CHAPTER 3—RIGHT TO HOLD HEALTH PLANS ACCOUNTABLE

SEC. 121. AMENDMENT TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended to read as follows:

“SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINATION, GRIEVANCES AND APPEALS.

“(a) CLAIMS PROCEDURE.—In accordance with regulations of the Secretary, every employee benefit plan shall—

“(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant; and

“(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

“(b) COVERAGE DETERMINATIONS UNDER GROUP HEALTH PLANS.—

“(1) PROCEDURES.—

“(A) IN GENERAL.—A group health plan or health insurance issuer conducting utilization review shall ensure that procedures are in place for—

“(i) making determinations regarding whether a participant or beneficiary is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the participant or beneficiary is required to pay with respect to such service;

“(ii) notifying a covered participant or beneficiary (or the authorized representative of such participant or beneficiary) and the treating health care professionals involved regarding determinations made under the plan or issuer and any additional payments that the participant or beneficiary may be required to make with respect to such service; and

“(iii) responding to requests, either written or oral, for coverage determinations or

for internal appeals from a participant or beneficiary (or the authorized representative of such participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary.

“(B) ORAL REQUESTS.—With respect to an oral request described in subparagraph (A)(iii), a group health plan or health insurance issuer may require that the requesting individual provide written evidence of such request.

“(2) TIMELINE FOR MAKING DETERMINATIONS.—

“(A) ROUTINE DETERMINATION.—A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where certain circumstances exist that are determined by the Secretary to be beyond control of the plan or issuer.

“(B) EXPEDITED DETERMINATION.—

“(i) IN GENERAL.—A prior authorization determination under this subsection shall be made within 72 hours, in accordance with the medical exigencies of the case, after a request is received by the plan or issuer under clause (ii) or (iii).

“(ii) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

“(iii) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies, that a determination under the procedures described in subparagraph (A) could seriously jeopardize the life or health of the participant or beneficiary.

“(C) CONCURRENT DETERMINATIONS.—A plan or issuer shall maintain procedures to certify or deny coverage of an extended stay or additional services.

“(D) RETROSPECTIVE DETERMINATION.—A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (1), the determination shall be made within 30 working days of the date on which the plan or issuer receives necessary information.

“(3) NOTICE OF DETERMINATIONS.—

“(A) ROUTINE DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and, consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

“(B) EXPEDITED DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(B), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary), and consistent with the medical exigencies of the case, to the treating health care professional involved within the 72 hour period described in paragraph (2)(B).

“(C) CONCURRENT REVIEWS.—With respect to the determination under a plan or issuer

under paragraph (2)(C) to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the participant or beneficiary involved (or the authorized representative of the participant or beneficiary) within 1 working day of the determination.

“(D) RETROSPECTIVE REVIEWS.—With respect to the retrospective review under a plan or issuer of a determination made under paragraph (2)(D), the plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and health care provider involved within 5 working days of the date on which such determination is made.

“(E) REQUIREMENTS OF NOTICE OF ADVERSE COVERAGE DETERMINATIONS.—A written notice of an adverse coverage determination under this subsection, or of an expedited adverse coverage determination under paragraph (2)(B), shall be provided to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and treating health care professional (if any) involved and shall include—

“(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

“(ii) the procedures for obtaining additional information concerning the determination; and

“(iii) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (d).

“(c) GRIEVANCES.—A group health plan or a health insurance issuer shall have written procedures for addressing grievances between the plan or issuer offering health insurance coverage in connection with a group health plan and a participant or beneficiary. Determinations under such procedures shall be non-appealable.

“(d) INTERNAL APPEAL OF COVERAGE DETERMINATIONS.—

“(1) RIGHT TO APPEAL.—

“(A) IN GENERAL.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary), may appeal any adverse coverage determination under subsection (b) under the procedures described in this subsection.

“(B) TIME FOR APPEAL.—A plan or issuer shall ensure that a participant or beneficiary has a period of not less than 180 days beginning on the date of an adverse coverage determination under subsection (b) in which to appeal such determination under this subsection.

“(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination under subsection (b) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to internal review under this subsection.

“(2) RECORDS.—A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement. Nothing in the preceding sentence shall be construed as preventing a plan and issuer from entering into an agreement under which the issuer agrees to assume responsibility for compliance with the require-

ments of this section and the plan is released from liability for such compliance.

“(3) ROUTINE DETERMINATIONS.—A group health plan or a health insurance issuer shall complete the consideration of an appeal of an adverse routine determination under this subsection not later than 30 working days after the date on which a request for such appeal is received.

“(4) EXPEDITED DETERMINATION.—

“(A) IN GENERAL.—An expedited determination with respect to an appeal under this subsection shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer under subparagraph (B) or (C).

“(B) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

“(C) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies of the case that a determination under the procedures described in paragraph (2) could seriously jeopardize the life or health of the participant or beneficiary.

“(5) CONDUCT OF REVIEW.—A review of an adverse coverage determination under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

“(6) LACK OF MEDICAL NECESSITY.—A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

“(7) NOTICE.—

“(A) IN GENERAL.—Written notice of a determination made under an internal review process shall be issued to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the treating health care professional not later than 2 working days after the completion of the review (or within the 72-hour period referred to in paragraph (4) if applicable).

“(B) ADVERSE COVERAGE DETERMINATIONS.—With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) shall include—

“(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

“(ii) the procedures for obtaining additional information concerning the determination; and

“(iii) notification of the right to an independent external review under subsection (e) and instructions on how to initiate such a review.

“(e) INDEPENDENT EXTERNAL REVIEW.—

“(1) ACCESS TO REVIEW.—

“(A) IN GENERAL.—A group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan shall have written procedures to

permit a participant or beneficiary (or the authorized representative of the participant or beneficiary) access to an independent external review with respect to an adverse coverage determination concerning a particular item or service (including a circumstance treated as an adverse coverage determination under subparagraph (B)) where—

“(i) the particular item or service involved—

“(I)(aa) would be a covered benefit, when medically necessary and appropriate under the terms and conditions of the plan, and the item or service has been determined not to be medically necessary and appropriate under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

“(bb)(AA) the amount of such item or service involved exceeds a significant financial threshold; or

“(BB) there is a significant risk of placing the life or health of the participant or beneficiary in jeopardy; or

“(II) would be a covered benefit, when not considered experimental or investigational under the terms and conditions of the plan, and the item or service has been determined to be experimental or investigational under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

“(ii) the participant or beneficiary has completed the internal appeals process under subsection (d) with respect to such determination.

“(B) FAILURE TO ACT.—The failure of a plan or issuer to issue a coverage determination under subsection (d)(6) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to independent external review under this subsection.

“(2) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

“(A) FILING OF REQUEST.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) who desires to have an independent external review conducted under this subsection shall file a written request for such a review with the plan or issuer involved not later than 30 working days after the receipt of a final denial of a claim under subsection (d). Any such request shall include the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary) for the release of medical information and records to independent external reviewers regarding the participant or beneficiary.

“(B) INFORMATION AND NOTICE.—Not later than 5 working days after the receipt of a request under subparagraph (A), or earlier in accordance with the medical exigencies of the case, the plan or issuer involved shall select an external appeals entity under paragraph (3)(A) that shall be responsible for designating an independent external reviewer under paragraph (3)(B).

“(C) PROVISION OF INFORMATION.—The plan or issuer involved shall forward necessary information (including medical records, any relevant review criteria, the clinical rationale consistent with the terms and conditions of the contract between the plan or issuer and the participant or beneficiary for the coverage denial, and evidence of the coverage of the participant or beneficiary) to the independent external reviewer selected under paragraph (3)(B).

“(D) NOTIFICATION.—The plan or issuer involved shall send a written notification to

the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the plan administrator, indicating that an independent external review has been initiated.

“(3) CONDUCT OF INDEPENDENT EXTERNAL REVIEW.—

“(A) DESIGNATION OF EXTERNAL APPEALS ENTITY BY PLAN OR ISSUER.—

“(i) **IN GENERAL.**—A plan or issuer that receives a request for an independent external review under paragraph (2)(A) shall designate a qualified entity described in clause (ii), in a manner designed to ensure that the entity so designated will make a decision in an unbiased manner, to serve as the external appeals entity.

“(ii) **QUALIFIED ENTITIES.**—A qualified entity shall be—

“(I) an independent external review entity licensed or credentialed by a State;

“(II) a State agency established for the purpose of conducting independent external reviews;

“(III) any entity under contract with the Federal Government to provide independent external review services;

“(IV) any entity accredited as an independent external review entity by an accrediting body recognized by the Secretary for such purpose; or

“(V) any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

“(B) DESIGNATION OF INDEPENDENT EXTERNAL REVIEWER BY EXTERNAL APPEALS ENTITY.—The external appeals entity designated under subparagraph (A) shall, not later than 30 days after the date on which such entity is designated under subparagraph (A), or earlier in accordance with the medical exigencies of the case, designate one or more individuals to serve as independent external reviewers with respect to a request received under paragraph (2)(A). Such reviewers shall be independent medical experts who shall—

“(i) be appropriately credentialed or licensed in any State to deliver health care services;

“(ii) not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review;

“(iii) have expertise (including age-appropriate expertise) in the diagnosis or treatment under review and, when reasonably available, be of the same specialty as the physician treating the participant or beneficiary or recommending or prescribing the treatment in question;

“(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the independent external review that is not contingent on the decision rendered by the reviewer; and

“(v) not be held liable for decisions regarding medical determinations (but may be held liable for actions that are arbitrary and capricious).

“(4) STANDARD OF REVIEW.—

“(A) **IN GENERAL.**—An independent external reviewer shall—

“(i) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and

“(ii) take into consideration appropriate and available information, including any evidence-based decision making or clinical practice guidelines used by the group health

plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature as defined in section 556(5) of the Federal Food, Drug, and Cosmetic Act.

“(B) NOTICE.—The plan or issuer involved shall ensure that the participant or beneficiary receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the independent external review.

“(5) TIMEFRAME FOR REVIEW.—

“(A) **IN GENERAL.**—The independent external reviewer shall complete a review of an adverse coverage determination in accordance with the medical exigencies of the case.

“(B) LIMITATION.—Notwithstanding subparagraph (A), a review described in such subparagraph shall be completed not later than 30 working days after the later of—

“(i) the date on which such reviewer is designated; or

“(ii) the date on which all information necessary to completing such review is received.

“(6) BINDING DETERMINATION.—The determination of an independent external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the independent external reviewer.

“(7) STUDY.—Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of a statistically appropriate sample of completed independent external reviews. Such study shall include an assessment of the process involved during an independent external review and the basis of decision-making by the independent external reviewer. The results of such study shall be submitted to the appropriate committees of Congress.

“(8) EFFECT ON CERTAIN PROVISIONS.—Nothing in this section shall be construed as affecting or modifying section 514 of this Act with respect to a group health plan.

“(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an independent external review by an independent external reviewer without first completing the internal review process.

“(g) DEFINITIONS.—In this section:

“(1) ADVERSE COVERAGE DETERMINATION.—The term ‘adverse coverage determination’ means a coverage determination under the plan which results in a denial of coverage or reimbursement.

“(2) COVERAGE DETERMINATION.—The term ‘coverage determination’ means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

“(3) GRIEVANCE.—The term ‘grievance’ means any complaint made by a participant or beneficiary that does not involve a coverage determination.

“(4) GROUP HEALTH PLAN.—The term ‘group health plan’ shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

“(5) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

“(6) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ has the meaning given such term in section 733(b)(2).

“(7) PRIOR AUTHORIZATION DETERMINATION.—The term ‘prior authorization determination’ means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

“(8) TREATING HEALTH CARE PROFESSIONAL.—The term ‘treating health care professional’ with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

“(9) UTILIZATION REVIEW.—The term ‘utilization review’ with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review.”

(b) ENFORCEMENT.—Section 502(c)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)(1)) is amended by inserting after “or section 101(e)(1)” the following: “, or fails to comply with a coverage determination as required under section 503(e)(6).”

(c) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by striking the item relating to section 503 and inserting the following new item:

“Sec. 503. Claims procedures, coverage determination, grievances and appeals.”

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after 1 year after the date of enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

Subtitle B—Genetic Information and Services

SEC. 201. SHORT TITLE.

This subtitle may be cited as the “Genetic Information Nondiscrimination in Health Insurance Act of 1999”.

SEC. 202. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION OR GENETIC SERVICES.—

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 702(a)(1)(F) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is amended by inserting before the period the following: “(including information about a request for or receipt of genetic services)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 111(a), is further amended by adding at the end the following:

“SEC. 715. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health

plan, shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services)."

(3) CONFORMING AMENDMENTS.—

(A) IN GENERAL.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 715."

(B) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by section 111(a), is further amended by inserting after the item relating to section 714 the following new item:

"Sec. 715. Prohibiting premium discrimination against groups on the basis of predictive genetic information."

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 702 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182) is amended by adding at the end the following:

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer."

(c) DEFINITIONS.—Section 733(d) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(d)) is amended by adding at the end the following:

"(5) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

"(A) the spouse of the individual;

"(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(6) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(7) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(8) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(9) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease."

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning 1 year after the date of the enactment of this Act.

SEC. 203. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

(1) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION IN THE GROUP MARKET.—

(A) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg-1(a)(1)(F)) is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services)".

(B) NO DISCRIMINATION IN PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart 2 of part A of title XXVII of the Public Health Service Act, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following new section:

"SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.

"A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services)."

(C) CONFORMING AMENDMENT.—Section 2702(b) of the Public Health Service Act (42 U.S.C. 300gg-1(b)) is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2707."

(D) LIMITATION ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg-1) is amended by adding at the end the following:

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part

of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer’s confidentiality practices, that shall include—

“(i) a description of an individual’s rights with respect to predictive genetic information;

“(ii) the procedures established by the plan or issuer for the exercise of the individual’s rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.”.

(2) DEFINITIONS.—Section 2791(d) of the Public Health Service Act (42 U.S.C. 300gg-91(d)) is amended by adding at the end the following:

“(15) FAMILY MEMBER.—The term ‘family member’ means, with respect to an individual—

“(A) the spouse of the individual;

“(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

“(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

“(16) GENETIC INFORMATION.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(17) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(18) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual’s genetic tests;

“(ii) information about genetic tests of family members of the individual; or

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(19) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”.

(b) AMENDMENT RELATING TO THE INDIVIDUAL MARKET.—The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-51 et seq.) (relating to other requirements), as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277) is amended—

(1) by redesignating such subpart as subpart 2; and

(2) by adding at the end the following:

“SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in individual health insurance coverage (including information about a request for or receipt of genetic services).

“(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer offering health insurance coverage in the individual market shall provide to the individual or dependent a de-

scription of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A health insurance issuer offering health insurance coverage in the individual market shall post or provide, in writing and in a clear and conspicuous manner, notice of the issuer’s confidentiality practices, that shall include—

“(i) a description of an individual’s rights with respect to predictive genetic information;

“(ii) the procedures established by the issuer for the exercise of the individual’s rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A health insurance issuer offering health insurance coverage in the individual market shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such issuer.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to—

(1) group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after 1 year after the date of enactment of this Act; and

(2) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after 1 year after the date of enactment of this Act.

SEC. 204. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

(a) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION OR GENETIC SERVICES.—

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 9802(a)(1)(F) of the Internal Revenue Code of 1986 is amended by inserting before the period the following: “(including information about a request for or receipt of genetic services)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 111(b), is further amended by adding at the end the following:

“SEC. 9814. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“A group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).”.

(B) CONFORMING AMENDMENT.—Section 9802(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or the receipt of genetic services), see section 9814.”.

(C) AMENDMENT TO TABLE OF SECTIONS.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 111(b), is further amended by adding at the end the following:

“Sec. 9814. Prohibiting premium discrimination against groups on the basis of predictive genetic information.”.

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 9802 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES; DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (e), of such predictive genetic information.

“(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan's confidentiality practices, that shall include—

“(i) a description of an individual's rights with respect to predictive genetic information;

“(ii) the procedures established by the plan for the exercise of the individual's rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information cre-

ated, received, obtained, maintained, used, transmitted, or disposed of by such plan.”.

(c) DEFINITIONS.—Section 9832(d) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(6) FAMILY MEMBER.—The term ‘family member’ means, with respect to an individual—

“(A) the spouse of the individual;

“(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

“(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

“(7) GENETIC INFORMATION.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(8) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(9) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual's genetic tests;

“(ii) information about genetic tests of family members of the individual; or

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(10) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”.

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning after 1 year after the date of the enactment of this Act.

Subtitle C—Healthcare Research and Quality

SEC. 301. SHORT TITLE.

This subtitle may be cited as the “Healthcare Research and Quality Act of 1999”.

SEC. 302. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended to read as follows:

“TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY “PART A—ESTABLISHMENT AND GENERAL DUTIES

“SEC. 901. MISSION AND DUTIES.

“(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality. In carrying out this

subsection, the Secretary shall redesignate the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality.

“(b) MISSION.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of healthcare services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. The Agency shall promote healthcare quality improvement by—

“(1) conducting and supporting research that develops and presents scientific evidence regarding all aspects of healthcare, including—

“(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

“(B) the outcomes, effectiveness, and cost-effectiveness of healthcare practices, including preventive measures and long-term care;

“(C) existing and innovative technologies;

“(D) the costs and utilization of, and access to healthcare;

“(E) the ways in which healthcare services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;

“(F) methods for measuring quality and strategies for improving quality; and

“(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

“(2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

“(3) advancing private and public efforts to improve healthcare quality.

“(c) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND PRIORITY POPULATIONS.—In carrying out subsection (b), the Director shall undertake and support research, demonstration projects, and evaluations with respect to the delivery of health services—

“(1) in rural areas (including frontier areas);

“(2) for low-income groups, and minority groups;

“(3) for children;

“(4) for elderly; and

“(5) for people with special healthcare needs, including disabilities, chronic care and end-of-life healthcare.

“(d) APPOINTMENT OF DIRECTOR.—There shall be at the head of the Agency an official to be known as the Director for Healthcare Research and Quality. The Director shall be appointed by the Secretary. The Secretary, acting through the Director, shall carry out the authorities and duties established in this title.

“SEC. 902. GENERAL AUTHORITIES.

“(a) IN GENERAL.—In carrying out section 901(b), the Director shall support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on healthcare, and on systems for the delivery of such care, including activities with respect to—

“(1) the quality, effectiveness, efficiency, appropriateness and value of healthcare services;

“(2) quality measurement and improvement;

“(3) the outcomes, cost, cost-effectiveness, and use of healthcare services and access to such services;

“(4) clinical practice, including primary care and practice-oriented research;

“(5) healthcare technologies, facilities, and equipment;

“(6) healthcare costs, productivity, organization, and market forces;

“(7) health promotion and disease prevention, including clinical preventive services;

“(8) health statistics, surveys, database development, and epidemiology; and

“(9) medical liability.

“(b) HEALTH SERVICES TRAINING GRANTS.—

“(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487 as well as other appropriated funds.

“(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers addressing the priority populations.

“(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

“(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

“(e) DISCLAIMER.—The Agency shall not mandate national standards of clinical practice or quality healthcare standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.

“(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, healthcare delivery systems, and individual preferences.

“PART B—HEALTHCARE IMPROVEMENT RESEARCH

“SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RESEARCH.

“(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems that it uses to assess healthcare research results, particularly methods or systems that it uses to rate the strength of the scientific evidence behind healthcare practice, recommendations in the research literature, and technology assessments. The Agency shall make methods or systems for evidence rating widely available. Agency publications containing healthcare recommendations shall indicate the level of substantiating evidence using such methods or systems.

“(b) HEALTHCARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—In order to address the full con-

tinuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

“(1) Healthcare Improvement Research Centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

“(2) Provider-based Research Networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate and promote quality improvement; and

“(3) other innovative mechanisms or strategies to link research with clinical practice.

“SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

“(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

“(1) SCIENTIFIC AND TECHNICAL SUPPORT.—In its role as the principal agency for healthcare research and quality, the Agency may provide scientific and technical support for private and public efforts to improve healthcare quality, including the activities of accrediting organizations.

“(2) ROLE OF THE AGENCY.—With respect to paragraph (1), the role of the Agency shall include—

“(A) the identification and assessment of methods for the evaluation of the health of—

“(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

“(ii) other populations, including those receiving long-term care services;

“(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

“(C) the compilation and dissemination of healthcare quality measures developed in the private and public sector;

“(D) assistance in the development of improved healthcare information systems;

“(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their healthcare; and

“(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

“(b) CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.—

“(1) IN GENERAL.—The Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, shall establish a program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in paragraph (2).

“(2) REQUIRED ACTIVITIES.—The activities referred to in this paragraph are the following:

“(A) The conduct of state-of-the-art clinical research for the following purposes:

“(i) To increase awareness of—

“(I) new uses of drugs, biological products, and devices;

“(II) ways to improve the effective use of drugs, biological products, and devices; and

“(III) risks of new uses and risks of combinations of drugs and biological products.

“(ii) To provide objective clinical information to the following individuals and entities:

“(I) Healthcare practitioners and other providers of healthcare goods or services.

“(II) Pharmacists, pharmacy benefit managers and purchasers.

“(III) Health maintenance organizations and other managed healthcare organizations.

“(IV) Healthcare insurers and governmental agencies.

“(V) Patients and consumers.

“(iii) To improve the quality of healthcare while reducing the cost of Healthcare through—

“(I) an increase in the appropriate use of drugs, biological products, or devices; and

“(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

“(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

“(C) Such other activities as the Secretary determines to be appropriate, except that grant funds may not be used by the Secretary in conducting regulatory review of new drugs.

“(c) REDUCING ERRORS IN MEDICINE.—The Director shall conduct and support research and build private-public partnerships to—

“(1) identify the causes of preventable healthcare errors and patient injury in healthcare delivery;

“(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

“(3) promote the implementation of effective strategies throughout the healthcare industry.

“SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.

“(a) IN GENERAL.—In carrying out 902(a), the Director shall—

“(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of healthcare, including the types of healthcare services Americans use, their access to healthcare services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population including rural residents and for the populations identified in section 901(c); and

“(2) develop databases and tools that provide information to States on the quality, access, and use of healthcare services provided to their residents.

“(b) QUALITY AND OUTCOMES INFORMATION.—

“(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

“(A) identify determinants of health outcomes and functional status, and their relationships to healthcare access and use, determine the ways and extent to which the priority populations enumerated in section 901(c) differ from the general population with respect to such variables, measure changes over time with respect to such variable, and monitor the overall national impact of changes in Federal and State policy on healthcare;

“(B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population including rural residents; and

“(C) provide reliable national estimates for children and persons with special healthcare needs through the use of supplements or periodic expansions of the survey.

In expanding the Medical Expenditure Panel Survey, as in existence on the date of enactment of this title, in fiscal year 2001 to collect information on the quality of care, the Director shall take into account any outcomes measurements generally collected by private sector accreditation organizations.

“(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of healthcare provided to the American people.”

“SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IMPROVEMENT.”

“(a) IN GENERAL.—In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall support research, evaluations and initiatives to advance—

“(1) the use of information systems for the study of healthcare quality, including the generation of both individual provider and plan-level comparative performance data;

“(2) training for healthcare practitioners and researchers in the use of information systems;

“(3) the creation of effective linkages between various sources of health information, including the development of information networks;

“(4) the delivery and coordination of evidence-based healthcare services, including the use of real-time healthcare decision-support programs;

“(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

“(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

“(7) the protection of individually identifiable information in health services research and healthcare quality improvement.”

“(b) DEMONSTRATION.—The Agency shall support demonstrations into the use of new information tools aimed at improving shared decision-making between patients and their care-givers.”

“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.”

“(a) PREVENTIVE SERVICES TASK FORCE.—

“(1) ESTABLISHMENT AND PURPOSE.—The Director may periodically convene a Preventive Services Task Force to be composed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the healthcare community, and updating previous clinical preventive recommendations.

“(2) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

“(3) OPERATION.—In carrying out its responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.

“(b) PRIMARY CARE RESEARCH.—

“(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the ‘Center’) that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

“(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research concerning—

“(A) the nature and characteristics of primary care practice;

“(B) the management of commonly occurring clinical problems;

“(C) the management of undifferentiated clinical problems; and

“(D) the continuity and coordination of health services.”

“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.”

“(a) IN GENERAL.—The Director shall promote innovation in evidence-based clinical practice and healthcare technologies by—

“(1) conducting and supporting research on the development, diffusion, and use of healthcare technology;

“(2) developing, evaluating, and disseminating methodologies for assessments of healthcare practices and healthcare technologies;

“(3) conducting intramural and supporting extramural assessments of existing and new healthcare practices and technologies;

“(4) promoting education, training, and providing technical assistance in the use of healthcare practice and healthcare technology assessment methodologies and results; and

“(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.”

“(b) SPECIFICATION OF PROCESS.—

“(1) IN GENERAL.—Not later than December 31, 2000, the Director shall develop and publish a description of the methodology used by the Agency and its contractors in conducting practice and technology assessment.

“(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

“(3) METHODOLOGY.—The Director, in developing assessment methodology, shall consider—

“(A) safety, efficacy, and effectiveness;

“(B) legal, social, and ethical implications;

“(C) costs, benefits, and cost-effectiveness;

“(D) comparisons to alternate technologies and practices; and

“(E) requirements of Food and Drug Administration approval to avoid duplication.

“(c) SPECIFIC ASSESSMENTS.—

“(1) IN GENERAL.—The Director shall conduct or support specific assessments of healthcare technologies and practices.

“(2) REQUESTS FOR ASSESSMENTS.—The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Health Care Financing Administration, the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management, and other public or private entities.

“(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded healthcare technologies, and for related activities.

“(4) ELIGIBLE ENTITIES.—An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, re-

search institutions and organizations, professional organizations, third party payers, governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS.”

“(a) REQUIREMENT.—

“(1) IN GENERAL.—To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

“(2) SPECIFIC ACTIVITIES.—The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

“(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

“(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and healthcare quality improvement initiatives;

“(C) set specific goals for participating agencies and departments to further health services research and healthcare quality improvement; and

“(D) strengthen the management of Federal healthcare quality improvement programs.”

“(b) STUDY BY THE INSTITUTE OF MEDICINE.—

“(1) IN GENERAL.—To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

“(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

“(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

“(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

“(B) to identify options and make recommendations to improve the efficiency and effectiveness of quality improvement programs through—

“(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

“(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

“(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

“(2) REQUIREMENTS.—

“(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

“(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

“(ii) not later than 24 months after the date of enactment of this title, of a final report containing recommendations.

“(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

“PART C—GENERAL PROVISIONS

“SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

“(a) ESTABLISHMENT.—There is established an advisory council to be known as the Advisory Council for Healthcare Research and Quality.

“(b) DUTIES.—

“(1) IN GENERAL.—The Advisory Council shall advise the Secretary and the Director with respect to activities proposed or undertaken to carry out the purpose of the Agency under section 901(b).

“(2) CERTAIN RECOMMENDATIONS.—Activities of the Advisory Council under paragraph (1) shall include making recommendations to the Director regarding—

“(A) priorities regarding healthcare research, especially studies related to quality, outcomes, cost and the utilization of, and access to, healthcare services;

“(B) the field of healthcare research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to healthcare quality; and

“(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

“(c) MEMBERSHIP.—

“(1) IN GENERAL.—The Advisory Council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Advisory Council shall be voting members other than the individuals designated under paragraph (3)(B) as ex officio members.

“(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

“(A) 4 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to healthcare;

“(B) 4 shall be individuals distinguished in the practice of medicine of which at least 1 shall be a primary care practitioner;

“(C) 3 shall be individuals distinguished in the other health professions;

“(D) 4 shall be individuals either representing the private healthcare sector, including health plans, providers, and purchasers or individuals distinguished as administrators of healthcare delivery systems;

“(E) 4 shall be individuals distinguished in the fields of healthcare quality improvement, economics, information systems, law, ethics, business, or public policy, including at least 1 individual specializing in rural aspects in 1 or more of these fields; and

“(F) 2 shall be individuals representing the interests of patients and consumers of healthcare.

“(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Advisory Council—

“(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

“(B) such other Federal officials as the Secretary may consider appropriate.

“(d) TERMS.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years. A member of the Council appointed under such subsection may continue to serve after the expiration of the term of the members until a successor is appointed.

“(e) VACANCIES.—If a member of the Advisory Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

“(f) CHAIR.—The Director shall, from among the members of the Advisory Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Advisory Council.

“(g) MEETINGS.—The Advisory Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Director or the chair.

“(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

“(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day during which such member is engaged in the performance of the duties of the Advisory Council.

“(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

“(i) STAFF.—The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

“SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

“(a) REQUIREMENT OF REVIEW.—

“(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

“(2) REPORTS TO DIRECTOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

“(b) APPROVAL AS PRECONDITION OF AWARDS.—The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

“(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

“(1) IN GENERAL.—The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

“(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

“(3) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section may continue in existence until otherwise provided by law.

“(4) QUALIFICATIONS.—Members of any peer-review group shall, at a minimum, meet the following requirements:

“(A) Such members shall agree in writing to treat information received, pursuant to their work for the group, as confidential information, except that this subparagraph shall not apply to public records and public information.

“(B) Such members shall agree in writing to recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of interest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer-review.

“(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed \$100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

“(e) REGULATIONS.—The Director shall issue regulations for the conduct of peer review under this section.

“SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

“(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

“(1) IN GENERAL.—To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 901(b), the Director shall establish standard methods for developing and collecting such data, taking into consideration—

“(A) other Federal health data collection standards; and

“(B) the differences between types of healthcare plans, delivery systems, healthcare providers, and provider arrangements.

“(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards

under paragraph (1) may affect the administration of other programs carried out by the Department of Health and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

“(b) STATISTICS AND ANALYSES.—The Director shall—

“(1) take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

“(2) publish, make available, and disseminate such statistics and analyses on as wide a basis as is practicable.

“(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this title pursuant to arrangements under which such entity will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

“SEC. 924. DISSEMINATION OF INFORMATION.

“(a) IN GENERAL.—The Director shall—

“(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title;

“(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

“(3) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

“(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to healthcare to public and private entities and individuals engaged in the improvement of healthcare delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

“(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

“(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

“(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Director) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such

person has consented (as determined under regulations of the Director) to its publication or release in other form.

“(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than \$10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

“SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

“(a) FINANCIAL CONFLICTS OF INTEREST.—With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this title, the Director shall by regulation define—

“(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

“(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

“(b) REQUIREMENT OF APPLICATION.—The Director may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out the program in involved.

“(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

“(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

“(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

“(d) APPLICABILITY OF CERTAIN PROVISIONS WITH RESPECT TO CONTRACTS.—Contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

“SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

“(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

“(1) DEPUTY DIRECTOR.—The Director may appoint a deputy director for the Agency.

“(2) OTHER OFFICERS AND EMPLOYEES.—The Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5, United States Code.

“(b) FACILITIES.—The Secretary, in carrying out this title—

“(1) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Director of General

Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

“(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

“(c) PROVISION OF FINANCIAL ASSISTANCE.—The Director, in carrying out this title, may make grants to public and nonprofit entities and individuals, and may enter into cooperative agreements or contracts with public and private entities and individuals.

“(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

“(1) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Director, in carrying out this title, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

“(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

“(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such periods as the Director deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

“(f) EXPERTS.—

“(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

“(2) TRAVEL EXPENSES.—

“(A) IN GENERAL.—Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(C) of title 5, United States Code.

“(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

“(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Director, in carrying out this title, may accept voluntary and uncompensated services.

“SEC. 927. FUNDING.

“(a) INTENT.—To ensure that the United States's investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a

corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsections (b) and (c) provide for a proportionate increase in healthcare research as the United States' investment in biomedical research increases.

“(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated \$250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2006.

“(c) EVALUATIONS.—In addition to amounts available pursuant to subsection (b) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available for a fiscal year.

“SEC. 928. DEFINITIONS.

“In this title:

“(1) ADVISORY COUNCIL.—The term ‘Advisory Council’ means the Advisory Council on Healthcare Research and Quality established under section 921.

“(2) AGENCY.—The term ‘Agency’ means the Agency for Healthcare Research and Quality.

“(3) DIRECTOR.—The term ‘Director’ means the Director for the Agency for Healthcare Research and Quality.”

SEC. 303. REFERENCES.

Effective upon the date of enactment of this Act, any reference in law to the “Agency for Health Care Policy and Research” shall be deemed to be a reference to the “Agency for Healthcare Research and Quality”.

Subtitle D—Enhanced Access to Health Insurance Coverage

SEC. 401. FULL DEDUCTION OF HEALTH INSURANCE COSTS FOR SELF-EMPLOYED INDIVIDUALS.

(a) IN GENERAL.—Section 162(l)(1) of the Internal Revenue Code of 1986 (relating to allowance of deductions) is amended to read as follows:

“(1) ALLOWANCE OF DEDUCTION.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer, his spouse, and his dependents.”

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 402. FULL AVAILABILITY OF MEDICAL SAVINGS ACCOUNTS.

(a) AVAILABILITY NOT LIMITED TO ACCOUNTS FOR EMPLOYEES OF SMALL EMPLOYERS AND SELF-EMPLOYED INDIVIDUALS.—

(1) IN GENERAL.—Section 220(c)(1)(A) of the Internal Revenue Code of 1986 (relating to eligible individual) is amended to read as follows:

“(A) IN GENERAL.—The term ‘eligible individual’ means, with respect to any month, any individual if—

“(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

“(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

“(I) which is not a high deductible health plan, and

“(II) which provides coverage for any benefit which is covered under the high deductible health plan.”

(2) CONFORMING AMENDMENTS.—

(A) Section 220(c)(1) of such Code is amended by striking subparagraphs (C) and (D).

(B) Section 220(c) of such Code is amended by striking paragraph (4) (defining small employer) and by redesignating paragraph (5) as paragraph (4).

(C) Section 220(b) of such Code is amended by striking paragraph (4) (relating to deduction limited by compensation) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

(b) REMOVAL OF LIMITATION ON NUMBER OF TAXPAYERS HAVING MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Section 220 of the Internal Revenue Code of 1986 (relating to medical savings accounts) is amended by striking subsections (i) and (j).

(2) MEDICARE+CHOICE.—Section 138 of such Code (relating to Medicare+Choice MSA) is amended by striking subsection (f).

(c) REDUCTION IN HIGH DEDUCTIBLE PLAN MINIMUM ANNUAL DEDUCTIBLE.—Section 220(c)(2)(A) of the Internal Revenue Code of 1986 (relating to high deductible health plan) is amended—

(1) by striking “\$1,500” in clause (i) and inserting “\$1,000”, and

(2) by striking “\$3,000” in clause (ii) and inserting “\$2,000”.

(d) INCREASE IN CONTRIBUTION LIMIT TO 100 PERCENT OF ANNUAL DEDUCTIBLE.—

(1) IN GENERAL.—Section 220(b)(2) of the Internal Revenue Code of 1986 (relating to monthly limitation) is amended to read as follows:

“(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to 1/2 of the annual deductible of the high deductible health plan of the individual.”

(2) CONFORMING AMENDMENT.—Section 220(d)(1)(A) of such Code is amended by striking “75 percent of”.

(e) LIMITATION ON ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Section 220(f)(4) of the Internal Revenue Code of 1986 (relating to additional tax on distributions not used for qualified medical expenses) is amended by adding at the end the following:

“(D) EXCEPTION IN CASE OF SUFFICIENT ACCOUNT BALANCE.—Subparagraph (A) shall not apply to any payment or distribution in any taxable year, but only to the extent such payment or distribution does not reduce the fair market value of the assets of the medical savings account to an amount less than the annual deductible for the high deductible health plan of the account holder (determined as of January 1 of the calendar year in which the taxable year begins).”

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 403. CARRYOVER OF UNUSED BENEFITS FROM CAFETERIA PLANS, FLEXIBLE SPENDING ARRANGEMENTS, AND HEALTH FLEXIBLE SPENDING ACCOUNTS.

(a) IN GENERAL.—Section 125 of the Internal Revenue Code of 1986 (relating to cafeteria plans) is amended by redesignating subsections (h) and (i) as subsections (i) and (j) and by inserting after subsection (g) the following new subsection:

“(h) ALLOWANCE OF CARRYOVERS OF UNUSED BENEFITS TO LATER TAXABLE YEARS.—

“(1) IN GENERAL.—For purposes of this title—

“(A) notwithstanding subsection (d)(2), a plan or other arrangement shall not fail to be treated as a cafeteria plan or flexible spending or similar arrangement, and

“(B) no amount shall be required to be included in gross income by reason of this section or any other provision of this chapter, solely because under such plan or other arrangement any nontaxable benefit which is unused as of the close of a taxable year may

be carried forward to 1 or more succeeding taxable years.

“(2) LIMITATION.—Paragraph (1) shall not apply to amounts carried from a plan to the extent such amounts exceed \$500 (applied on an annual basis). For purposes of this paragraph, all plans and arrangements maintained by an employer or any related person shall be treated as 1 plan.

“(3) ALLOWANCE OF ROLLOVER.—

“(A) IN GENERAL.—In the case of any unused benefit described in paragraph (1) which consists of amounts in a health flexible spending account or dependent care flexible spending account, the plan or arrangement shall provide that a participant may elect, in lieu of such carryover, to have such amounts distributed to the participant.

“(B) AMOUNTS NOT INCLUDED IN INCOME.—Any distribution under subparagraph (A) shall not be included in gross income to the extent that such amount is transferred in a trustee-to-trustee transfer, or is contributed within 60 days of the date of the distribution, to—

“(i) a qualified cash or deferred arrangement described in section 401(k),

“(ii) a plan under which amounts are contributed by an individual's employer for an annuity contract described in section 403(b),

“(iii) an eligible deferred compensation plan described in section 457, or

“(iv) a medical savings account (within the meaning of section 220).

Any amount rolled over under this subparagraph shall be treated as a rollover contribution for the taxable year from which the unused amount would otherwise be carried.

“(C) TREATMENT OF ROLLOVER.—Any amount rolled over under subparagraph (B) shall be treated as an eligible rollover under section 220, 401(k), 403(b), or 457, whichever is applicable, and shall be taken into account in applying any limitation (or participation requirement) on employer or employee contributions under such section or any other provision of this chapter for the taxable year of the rollover.

“(4) COST-OF-LIVING ADJUSTMENT.—In the case of any taxable year beginning in a calendar year after 1999, the \$500 amount under paragraph (2) shall be adjusted at the same time and in the same manner as under section 415(d)(2), except that the base period taken into account shall be the calendar quarter beginning October 1, 1998, and any increase which is not a multiple of \$50 shall be rounded to the next lowest multiple of \$50.”

“(5) APPLICABILITY.—This subsection shall apply to taxable years beginning after December 31, 1999.”

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 404. PERMITTING CONTRIBUTION TOWARDS MEDICAL SAVINGS ACCOUNT THROUGH FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM (FEHBP).

(a) GOVERNMENT CONTRIBUTION TO MEDICAL SAVINGS ACCOUNT.—

(1) IN GENERAL.—Section 8906 of title 5, United States Code, is amended by adding at the end the following:

“(j)(1) In the case of an employee or annuitant who is enrolled in a catastrophic plan described by section 8903(5), there shall be a Government contribution under this subsection to a medical savings account established or maintained for the benefit of the individual. The contribution under this subsection shall be in addition to the Government contribution under subsection (b).

“(2) The amount of the Government contribution under this subsection with respect to an individual is equal to the amount by which—

“(A) the maximum contribution allowed under subsection (b)(1) with respect to any employee or annuitant, exceeds

“(B) the amount of the Government contribution actually made with respect to the individual under subsection (b) for coverage under the catastrophic plan.

“(3) The Government contributions under this subsection shall be paid into a medical savings account (designated by the individual involved) in a manner that is specified by the Office and consistent with the timing of contributions under subsection (b).

“(4) Subsections (f) and (g) shall apply to contributions under this section in the same manner as they apply to contributions under subsection (b).

“(5) For the purpose of this subsection, the term ‘medical savings account’ has the meaning given such term by section 220(d) of the Internal Revenue Code of 1986.”.

(2) ALLOWING PAYMENT OF FULL AMOUNT OF CHARGE FOR CATASTROPHIC PLAN.—Section 8906(b)(2) of such title is amended by inserting “(or 100 percent of the subscription charge in the case of a catastrophic plan)” after “75 percent of the subscription charge”.

(b) OFFERING OF CATASTROPHIC PLANS.—

(1) IN GENERAL.—Section 8903 of title 5, United States Code, is amended by adding at the end the following:

“(5) CATASTROPHIC PLANS.—One or more plans described in paragraph (1), (2), or (3), but which provide benefits of the types referred to by paragraph (5) of section 8904(a), instead of the types referred to in paragraphs (1), (2), and (3) of such section.”.

(2) TYPES OF BENEFITS.—Section 8904(a) of such title is amended by inserting after paragraph (4) the following new paragraph:

“(5) CATASTROPHIC PLANS.—Benefits of the types named under paragraph (1) or (2) of this subsection or both, to the extent expenses covered by the plan exceed \$500.”.

(3) DETERMINING LEVEL OF GOVERNMENT CONTRIBUTIONS.—Section 8906(b) of such title is amended by adding at the end the following: “Subscription charges for medical savings accounts shall be deemed to be the amount of Government contributions made under subsection (j)(2).”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to contract terms beginning on or after January 1, 2000.

BURNS AMENDMENT NO. 704

(Ordered to lie on the table.)

Mr. BURNS submitted an amendment intended to be proposed by him to the bill, S. 1233, *supra*; as follows:

On page 76, between lines 6 and 7, insert the following:

SEC. 7. SENSE OF SENATE ON LAMB MEAT IMPORTS.—It is the sense of the Senate that—

(1) there is an overabundance of foreign lamb meat being imported into the United States;

(2) the glut of imported lamb meat is severely harming domestic producers and the domestic agricultural industry;

(3) the sheep industry filed a petition to take action under section 201 of the Trade Act of 1974 (19 U.S.C. 2251) to prevent further loss of market share due to the enormous quantities of lamb being imported into the United States from New Zealand and Australia;

(4) on February 9, 1999, the International Trade Commission voted unanimously that lamb imports are a threat to the sheep industry in the United States;

(5) on March 26, 1999, the International Trade Commission voted to support 4 years of market stability in the marketing of lamb meat;

(6) several remedies have been offered to achieve this market stability, including tariff rate quotas and *ad-valorem* tariffs;

(7) the efforts of the sheep industry in the United States should be supported;

(8) although international military issues have recently consumed much time and consideration, with the Kosovo agreement now in place, Congress should turn its attention to domestic matters;

(9) the problem of the overabundance of foreign lamb meat in the United States has important consequences for imports and international trade; and

(10) the remedy that will provide the greatest practicable assistance to the domestic lamb industry should be implemented as soon as practicable.

NOTICES OF HEARINGS

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. JEFFORDS. Mr. President, I would like to announce for information of the Senate and the public that a hearing of the Senate Committee on Health, Education, Labor, and Pensions will be held on Tuesday, June 22, 1999, 9:30 a.m., in SD-628 of the Senate Dirksen Building. The subject of the hearing is “ESEA: Professional Development”. For further information, please call the committee, 202/224-5375.

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. JEFFORDS. Mr. President, I would like to announce for information of the Senate and the public that a hearing of the Senate Committee on Health, Education, Labor and Pensions, Subcommittee on Aging will be held on June 22, 1999, 2:30 p.m., in SD-628 of the Senate Dirksen Building. The subject of the hearing is “Older Americans Act”. For further information, please call the committee, 202/224-5375.

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. JEFFORDS. Mr. President, I would like to announce for information of the Senate and the public that a hearing of the Senate Committee on Health, Education, Labor, and Pensions will be held on Wednesday, June 23, 1999, 9:30 a.m., in SD-628 of the Senate Dirksen Building. The subject of the hearing is “ESEA: Title VI”. For further information, please call the committee, 202/224-5375.

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. JEFFORDS. Mr. President, I would like to announce that the Senate Committee on Agriculture, Nutrition, and Forestry will meet on June 24, 1999 in SR-328A at 9:30 a.m. The purpose of this meeting will be to discuss Agriculture issues related to a variety of trade topics.

ADDITIONAL STATEMENTS

TRIBUTE TO BOBBIE FOUST

• Mr. McCONNELL. Mr. President, I rise today to pay tribute to Roberta Foust, or “Bobbie” as she is known to

her many friends and readers. With her recent retirement from The Paducah Sun, Bobbie completes a distinguished career as a journalist.

Her byline has long been a familiar one to news readers in the western part of Kentucky. She worked for The Calvert News in Calvert City in the 1960’s. In 1972, she began working as a reporter and photographer for The Tribune Courier in Marshall County, in the heart of Kentucky’s Western Lakes region. After 5 years, she moved to the rival Marshall County Messenger, where she was responsible for all news content, layout, and design. She returned to The Tribune Courier in a similar capacity in 1979. In 1988, she became the editor of the weekly Herald Ledger in Eddyville, a position she held until the local ownership sold the paper in 1991.

Bobbie then joined the largest newspaper in far Western Kentucky, The Paducah Sun, a daily with a circulation of 31,000. With the Sun, Bobbie served as a general assignment reporter. In this position, she worked in Marshall, Lyon, and other lakes-area counties. Besides the usual broad assortment of news she covered in her day-to-day duties, Bobbie covered certain continuing stories, and developed an in-depth knowledge in these areas that was widely recognized. Among these were the Land Between the Lakes and the role of the Tennessee Valley Authority in LBL and Western Kentucky. During this time, Bobbie earned broad respect in the region she covered, as well as at TVA headquarters in Knoxville and Washington.

I have not only been a regular reader of Bobbie’s, but have often been covered in her stories. Over the years, I have had the opportunity to get to know her first-hand, and feel that I am in a uniquely qualified position to comment upon her journalistic legacy. Bobbie has earned a reputation of persistence, thoroughness, and objectivity—the three lodestars of her profession. Always firm in getting the story for her readers, she was unflappably cordial in personal demeanor in the performance of her duties.

Bobbie’s retirement plans include the possibility of taking some college course work, and hopefully, the role of occasional contributor to The Paducah Sun. Along with Bobbie’s husband, Ray, and children, Donna, Terrie, Jackie, and Dennis, I wish Bobbie an enjoyable and productive retirement. I ask that my colleagues join me in recognizing the career of this outstanding Kentuckian.●

TWENTY-FIFTH ANNIVERSARY OF BREAD FOR THE WORLD

• Mr. HARKIN. Mr. President, for 25 years, Bread for the World has been putting principles of faith to work in pursuit of justice for the world’s hungry people. Bread for the World members are now in Washington for their